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**Federal Aviation
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Aircraft Certification Systems Evaluation Program (ACSEP) FY 1998 Report

Prepared by
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TABLE OF CONTENTS

<u>Section</u>	<u>Page</u>
TABLE OF CONTENTS	<i>i</i>
LIST OF FIGURES	<i>iii</i>
LIST OF TABLES	<i>vi</i>
EXECUTIVE SUMMARY	<i>1</i>
FY 1998 Report	<i>7</i>
1. Introduction.....	<i>7</i>
1.1 Report Structure.....	<i>7</i>
1.2 Program Overview of ACSEP.....	<i>8</i>
1.3 The Data Collected During an ACSEP Evaluation	<i>13</i>
2. Conclusions of Data Analysis	<i>15</i>
3. Data Analysis — Manufacturing Facilities.....	<i>17</i>
3.1 Safety Related Findings.....	<i>17</i>
3.2 Systemic Issues (Findings vs. Systemic Observations).....	<i>17</i>
3.3 Isolated and Systemic Issues	<i>20</i>
3.4 Comparison of Facility Types	<i>21</i>
3.4.1 Complexity of Systems.....	<i>22</i>
3.4.2 Systemic Issues	<i>23</i>
3.4.3 Isolated Observations.....	<i>27</i>
3.4.4 FAR-based Observations.....	<i>28</i>
3.5 Subsystem Issues	<i>29</i>
3.5.1 Similarity Among Facility Types.....	<i>29</i>
3.5.2 Areas of Significant Difference Among Facility Types	<i>34</i>
3.5.3 Facility Perspective.....	<i>34</i>
3.6 Analysis of Evaluation Criteria.....	<i>38</i>
3.6.1 A View of the Industry	<i>38</i>
3.6.1.1 Systemic Findings and Observations.....	<i>39</i>
3.6.1.2 Isolated Observations	<i>41</i>
3.6.1.3 FAR-based Observations	<i>43</i>
3.6.2 A Facility Focus	<i>44</i>
3.6.2.1 Systemic Findings and Observations.....	<i>44</i>
3.6.2.2 Isolated Observations	<i>49</i>
3.6.3 Summary of Criteria Issues.....	<i>52</i>

3.7	Trend Analysis	53
3.7.1	Systemic Issues.....	54
3.7.1.1	Systemic Issue Trends at the Subsystem Level	57
3.7.1.2	Systemic Issue Trends at the Criteria Level	60
3.7.2	Isolated Observations	62
3.7.3	FAR-based Observations	65
3.8	Internal Audit.....	68
3.8.1	What is the Impact of a Discrepant Internal Audit Program?.....	68
3.8.2	Does an Internal Audit Program Reduce Findings and Observations?	72
3.9	Analysis of International Facilities.....	74
4.	Data Analysis — Delegated Facilities.....	76
4.1	Designated Alteration Stations (DAS) Facilities	76
4.2	Special Federal Aviation Regulation No. 36 (SFAR-36) Facilities	78
5.	Significant Events During the Fiscal Year	80
6.	Improvement Emphasis.....	81
6.1	Industry Feedback.....	81
6.2	Lessons Learned	84
 APPENDIX A - HISTORY AND BACKGROUND OF ACSEP		A-1
A1.	Background	A-1
A2.	Overview.....	A-1
A3.	Evaluations and Evaluators	A-4
 APPENDIX B - DEFINITIONS.....		B-1
 APPENDIX C - CRITERIA HAVING FINDINGS OR OBSERVATIONS.....		C-1
C1.	Manufacturing Facilities.....	C-1
C2.	Delegated Facilities	C-36
 APPENDIX D - CORRELATION BETWEEN FACILITY COMPLEXITY AND THE PROBABILITY OF SYSTEMIC ISSUES.....		D-1
 APPENDIX E - ANALYSIS METHODS AND ASSUMPTIONS.....		e-1
E1.	Sample/Inferential Error	E-1
E2.	Sample/Inferential Error When Reporting the Number of Noncompliances.....	E-1
E3.	Sample Error When Reporting Facility Frequencies and Other Finite Populations.....	E-3
E4.	Pooling of Multi-year Data	E-4
E5.	Selection of the Confidence Interval.....	E-4

LIST OF FIGURES

<i>Figure 1-1.— Growth in annual ACSEP evaluations.</i>	9
<i>Figure 1-2.— Distribution of ACSEP evaluations at manufacturing facilities by facility type — domestic and international combined.</i>	10
<i>Figure 1-3.— Distribution of ACSEP evaluations at manufacturing facilities by directorate — domestic and international combined.</i>	11
<i>Figure 1-4.— Distribution of ACSEP evaluations at delegated facilities by delegation type.</i>	12
<i>Figure 1-5.— Distribution of ACSEP evaluations at delegated facilities by directorate.</i>	12
<i>Figure 3-1.— Systemic findings – all facility types.</i>	18
<i>Figure 3-2.— Systemic observations – all facility types.</i>	19
<i>Figure 3-3.— Systemic findings and systemic observations – all facility types.</i>	19
<i>Figure 3-4.— Frequency distribution of isolated observations – all facility types.</i>	20
<i>Figure 3-5.— Systemic issues and system complexity are related.</i>	22
<i>Figure 3-6.— Comparison between the facility types – adjusted for complexity.</i>	23
<i>Figure 3-7.— Comparison of the percentages of facilities with at least one systemic issue.</i>	24
<i>Figure 3-8.— Cyclical change in the percentage of PC holders with systemic issues from FY 1995 to FY 1998.</i>	25
<i>Figure 3-9.— Reduction in percentage of priority parts suppliers with systemic issues from FY 1995 to FY 1998.</i>	26
<i>Figure 3-10.— Comparison of isolated observation rate for the various facility types.</i>	27
<i>Figure 3-11.— Comparison of FAR-based observation rate for the various facility types.</i>	28
<i>Figure 3-12.— Systemic issues – APIS holders.</i>	29
<i>Figure 3-13.— Systemic issues – PC holders.</i>	30
<i>Figure 3-14.— Systemic issues – PMA holders.</i>	30
<i>Figure 3-15.— Systemic issues – priority parts suppliers.</i>	31
<i>Figure 3-16.— Systemic issues – TSO authorization holders.</i>	31
<i>Figure 3-17.— Systemic issues – all facility types.</i>	32
<i>Figure 3-18.— Systemic issues at PC holders adjusted for applicability.</i>	36
<i>Figure 3-19.— Systemic issues at PMA holders adjusted for applicability.</i>	36
<i>Figure 3-20.— Systemic issues at priority parts suppliers adjusted for applicability.</i>	37
<i>Figure 3-21.— Systemic issues at TSO authorization holders adjusted for applicability.</i>	37

<i>Figure 3-22.—Comparison of the various facility types – percentage of facilities with systemic issues in the criteria.</i>	<i>52</i>
<i>Figure 3-23.—Preliminary trend data for systemic issues — overall.</i>	<i>54</i>
<i>Figure 3-24.—Preliminary trend data for systemic issues — PC holders.</i>	<i>55</i>
<i>Figure 3-25.—Preliminary trend data for systemic issues — PMA holders.</i>	<i>55</i>
<i>Figure 3-26.—Preliminary trend data for systemic issues — priority part suppliers.</i>	<i>56</i>
<i>Figure 3-27.—Preliminary trend data for systemic issues — TSO authorizations.</i>	<i>56</i>
<i>Figure 3-28.—Preliminary trend data for systemic issues — overall.</i>	<i>57</i>
<i>Figure 3-29.—Preliminary trend data for systemic issues —supplier control subsystem.</i>	<i>58</i>
<i>Figure 3-30.—Preliminary trend data for systemic issues — manufacturing processes subsystem.</i>	<i>58</i>
<i>Figure 3-31.—Preliminary trend data for systemic issues — design data control subsystem.</i>	<i>59</i>
<i>Figure 3-32.—Preliminary trend data for systemic issues — testing subsystem.</i>	<i>59</i>
<i>Figure 3-33.—Preliminary trend data for systemic issues — statistical quality control (SQC) subsystem.</i>	<i>60</i>
<i>Figure 3-34.—Preliminary trend data for systemic issues —Criteria 10Q1: Initial & periodic evaluations of suppliers.</i>	<i>61</i>
<i>Figure 3-35.—Preliminary trend data for systemic issues —Criteria 11Q1: Control of nonconforming products.</i>	<i>61</i>
<i>Figure 3-36.—Preliminary trend data for isolated observations —overall.</i>	<i>62</i>
<i>Figure 3-37.—Preliminary trend data for isolated observations —PC holders.</i>	<i>63</i>
<i>Figure 3-38.—Preliminary trend data for isolated observations —PMA holders.</i>	<i>63</i>
<i>Figure 3-39.—Preliminary trend data for isolated observations —priority part suppliers.</i>	<i>64</i>
<i>Figure 3-40.—Preliminary trend data for isolated observations —TSO authorization holders.</i>	<i>64</i>
<i>Figure 3-41.—Preliminary trend data for FAR-based observations —overall.</i>	<i>65</i>
<i>Figure 3-42.—Preliminary trend data for FAR-based observations —PC holders.</i>	<i>66</i>
<i>Figure 3-43.—Preliminary trend data for FAR-based observations —PMA holders.</i>	<i>66</i>
<i>Figure 3-44.—Preliminary trend data for FAR-based observations —TSO authorization holders.</i>	<i>67</i>
<i>Figure 3-45.—Comparison of systemic issues for facilities with effective and ineffective internal audit programs.</i>	<i>69</i>
<i>Figure 3-46.—Comparison of the number of systemic issues at facilities with effective and ineffective internal audit programs (all facilities).</i>	<i>70</i>

<i>Figure 3-47.—Comparison of the number of systemic issues at facilities with effective and ineffective internal audit programs (facilities with at least one systemic issue in other than the internal audit subsystem).</i>	<i>71</i>
<i>Figure 3-48.—Partial frequency distribution of facilities with systemic issues other than within the internal audit subsystem.....</i>	<i>71</i>
<i>Figure 3-49.—The affect of an internal audit program on compliance.....</i>	<i>72</i>
<i>Figure 3-50.— The affect of an internal audit program on the number of findings and systemic observations.....</i>	<i>73</i>
<i>Figure 3-51.—Systemic issues — international facilities.</i>	<i>74</i>
<i>Figure 3-52.—Systemic issues — international facilities.</i>	<i>75</i>
<i>Figure 4-1.— Findings and systemic observations — DAS facilities.....</i>	<i>76</i>
<i>Figure 4-2.— Proportion of DAS facilities with Findings and systemic observations.</i>	<i>77</i>
<i>Figure 4-3.— Findings and systemic observations — DAS facilities.....</i>	<i>78</i>
<i>Figure 4-4.— Proportion of DAS facilities with Findings and systemic observations.</i>	<i>79</i>
<i>Figure 6-1.— Distribution of industry feedback using old categories.</i>	<i>82</i>
<i>Figure 6-2.— Distribution of industry feedback using new categories.</i>	<i>82</i>
<i>Figure 6-3.— ACSEP as graded by industry using old categories.....</i>	<i>83</i>
<i>Figure 6-4.— ACSEP as graded by industry using new categories.</i>	<i>83</i>
<i>Figure 6-5.— Trend of lessons learned—favorable experiences.....</i>	<i>84</i>
<i>Figure 6-6.— Trend of lessons learned—no difficulties with Order 8100.7.</i>	<i>84</i>
<i>Figure 6-7.— Trend of lessons learned—evaluation completed.....</i>	<i>85</i>
<i>Figure 6-8.— Trend of lessons learned—no new criteria needed.</i>	<i>85</i>
<i>Figure 6-9.— Lessons learned – ACSEP evaluations at domestic vs. international facilities.</i>	<i>86</i>
<i>Figure 6-10.—Distribution of subsystems not evaluated.</i>	<i>87</i>
 <i>Figure A- 1.—Evaluation criteria distribution within the six major system elements of ACSEP.....</i>	 <i>A-2</i>
<i>Figure A- 2. —Evaluation criteria distribution within the 17 subsystems of ACSEP for manufacturing facilities.....</i>	<i>A-3</i>
<i>Figure A- 3. —Evaluation criteria distribution within the 10 subsystems of ACSEP for Delegated Facilities.....</i>	<i>A-4</i>
 <i>Figure D-1. —Scatter diagram of systemic findings/observations vs. number of evaluators present at ACSEP evaluations.....</i>	 <i>D-2</i>

LIST OF TABLES

TABLE 1-1. —The population of PAHs for fiscal years 1993 through 1998	10
TABLE 1-2. —The population of delegated facilities for fiscal 1998.....	12
TABLE 3-1. —Top ten percentile of isolated issues compared to the top ten percentile of systemic issues	21
TABLE 3-2. —Summary of the most prevalent systemic issues	32
TABLE 3-3. —Most frequently cited subsystems with systemic issues – FY 1995 to FY 1998.....	33
TABLE 3-4. —Predominant systemic findings and observations	39
TABLE 3-5. —Four-year trend of most predominant systemic issues – by criteria	40
TABLE 3-6. —Predominant isolated observations	41
TABLE 3-7. —Four-year trend of most predominant isolated observations – by criteria	42
TABLE 3-8. —Predominant FAR-based observations.....	43
TABLE 3-9. —Predominant systemic findings and observations — PC holders.....	45
TABLE 3-10.—Predominant systemic findings and observations — PMA holders	46
TABLE 3-11.—Predominant systemic findings and observations — priority parts suppliers.....	47
TABLE 3-12.—Predominant systemic findings and observations — TSO authorization holders.....	48
TABLE 3-13.—Predominant isolated observations — PC holders	49
TABLE 3-14.—Predominant isolated observations — PMA holders	50
TABLE 3-15.—Predominant isolated observations — priority parts suppliers	50
TABLE 3-16.—Predominant isolated observations — TSO authorization holders.....	51
TABLE 3-17.—Estimated reduction in facilities with systemic issues.....	57
TABLE 3-18.—Preliminary four-year trend of systemic issues—criteria level.....	60
TABLE 6-1. —Comments received from lessons learned sheets	88
TABLE C- 1.—Systemic findings and observations.....	C-2
TABLE C- 2.—Isolated observations.....	C-7
TABLE C- 3.—FAR-based observations.....	C-10
TABLE C- 4.—Systemic findings and observations—APIS holders only.....	C-12
TABLE C- 5.—Systemic findings and observations—PC holders only.....	C-13
TABLE C- 6.—Systemic findings and observations—PMA holders only.....	C-16
TABLE C- 7.—Systemic findings and observations—priority parts suppliers only.....	C-20

<i>TABLE C- 8. —Systemic findings and observations—TSO authorization holders only</i>	<i>C-22</i>
<i>TABLE C- 9. —Isolated observations—APIS holders only</i>	<i>C-25</i>
<i>TABLE C- 10.—Isolated observations—PC holders only</i>	<i>C-26</i>
<i>TABLE C- 11.— Isolated observations—PMA holders only</i>	<i>C-28</i>
<i>TABLE C- 12.— Isolated observations— priority parts suppliers only</i>	<i>C-29</i>
<i>TABLE C- 13.— Isolated observations—TSO authorization holders only.....</i>	<i>C-30</i>
<i>TABLE C- 14.— Systemic findings and observations –international facilities</i>	<i>C-32</i>
<i>TABLE C- 15.—Isolated observations –international facilities</i>	<i>C-34</i>
<i>TABLE C- 16.—Systemic findings and observations – delegated facilities</i>	<i>C-36</i>
<i>TABLE C- 17.—Isolated findings and observations – delegated facilities</i>	<i>C-38</i>
<i>TABLE C- 18.—Systemic findings and observations – DAS facilities</i>	<i>C-39</i>
<i>TABLE C- 19.—Systemic findings and observations – SFAR-36 facilities.....</i>	<i>C-40</i>
<i>TABLE C- 20.—Systemic findings and observations – DOA facilities</i>	<i>C-40</i>
<i>TABLE C- 21.— Isolated findings and observations – DAS facilities</i>	<i>C-41</i>
<i>TABLE C- 22.— Isolated findings and observations – SFAR-36 facilities</i>	<i>C-42</i>
<i>TABLE C- 23.— Isolated findings and observations – DOA facilities</i>	<i>C-42</i>

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EXECUTIVE SUMMARY

This report documents the fiscal year (FY) 1998 results of the Federal Aviation Administration (FAA) Aircraft Certification Service (AIR) Aircraft Certification Systems Evaluation Program (ACSEP).

The ACSEP was designed to determine if FAA production approval holders, their priority parts suppliers, and delegated facilities are complying with the requirements of applicable Federal Aviation Regulations (FAR) and the procedures established to meet those requirements. It also surveys the application of standardized industry practices, not required by the FAR or FAA-approved data, to identify national trends that may require development of new or revised regulations, policy, or guidance. The elements of the evaluation are referred to as criteria. Data was collected on noncompliance and applicability with respect to those criteria. The history and background of ACSEP, the structure of the evaluation teams, and departmental interactions are discussed in *Appendix A*.

During an ACSEP evaluation, the actual operating practices of a facility are compared to the FAR, FAA-approved data, and the facility's internal procedures. Any inconsistency discovered (termed "issue" in this report) is classified and recorded. An issue is classified by its type and the subsystem under which it is noted. There are five issue types:

Safety Finding - an issue that compromises immediate continued operational safety.

Systemic Finding - an issue that is systemic in nature, i.e., is pervasive, repeatable, or represents a breakdown in the quality management system. For an issue to be categorized a finding, it must also be a noncompliance to a FAR or FAA-approved data (or noncompliance with the procurement instrument when a facility is a supplier).

Systemic Observation - an issue that is systemic in nature and is a noncompliance to facility procedures that are not FAA approved.

Isolated Observation - an issue that is of an isolated or nonsystemic nature, i.e., isolated to a particular person and/or timeframe and does not represent a breakdown in the quality management system. For an issue to be categorized an isolated observation, it must also be an isolated noncompliance to a FAR or FAA-approved data (or a noncompliance with the procurement instrument when a facility is a supplier).

FAR-Based Observation - the discovery of FAA-approved data that is inconsistent with the FAR.

The second form of classification of an issue is the subsystem under which it is discovered. In total, there are 17 subsystems that represent a quality management system:

- Organization and Responsibility
- Design Data Control
- Software Quality Assurance
- Manufacturing Processes
- Special Manufacturing Processes
- Statistical Quality Control (SQC)
- Tool and Gauge
- Testing
- Nondestructive Inspection
- Supplier Control
- Nonconforming Material
- Material Handling/Storage
- Airworthiness Determination
- FAR Reporting Requirements
- Internal Audit
- Global Production
- Manufacturing Maintenance Facility

Each subsystem is further divided into “criteria.” In order to fully examine the detailed areas within each of the 17 subsystems, the criteria were developed with extensive assistance from industry. A process also exists to identify potential new criteria should the existing criteria not address a particular functional area within a subsystem. The subclassification of issues into the detailed criteria allows the FAA to identify specific areas of concern and allows industry to focus corrective action on those specific areas of concern. For example, the supplier control subsystem is composed of 16 individual criteria. Specific areas of concern that may be identified include: the use of approved suppliers; periodic evaluations of suppliers; flowdown of applicable technical and quality requirements to suppliers; raw material verification; and others.

Through the use of detailed criteria and their relevant subsystems, quality management systems can be evaluated in a consistent manner. Annually, the data is collected and analyzed for trends. In FY 1995, the data was baselined so that the effectiveness of any industry actions to address issues previously reported can be detected and measured. Where appropriate, the analyses presented in this report were performed at both the criteria and the subsystem level.

Of the almost 1,000 findings and observations recorded at the 580 facilities evaluated in FY 1998, only 5 identified significant safety concerns, i.e., findings for which immediate corrective action was required. The balance of the issues reported were not considered an immediate safety concern. The data collected did, however, indicate some very definite trends. Almost one-fourth of all findings and observations were recorded in the manufacturing processes subsystem: the most problematic area for all of the manufacturing facility types. One-half of the findings and observations were recorded within five additional subsystems: supplier control, tool and gauge, design data control, nonconforming material, and material handling/storage. In addition, the issues within these subsystems were concentrated within a few criteria.

The subsystems and criteria where the most issues were reported are as follows:

Manufacturing Processes - Specific functions and operations necessary for the fabrication and inspection of parts and assemblies (e.g., machining, riveting, and assembling).

- Completed products/parts did not have proper identification markings.
- Work instructions did not adequately control the manufacturing process.
- Records were not generated or maintained for all significant provisions of the quality/inspection program which have an affect on control of FAA-approved design data, or if applicable, purchase order requirements.
- Insufficient inspection methods and plans to ensure that parts were inspected for conformity with FAA-approved design data.
- Required inspections or tests not satisfactorily accomplished prior to final acceptance of completed parts or products.

Supplier Control - The system by which the evaluated facility ensures that supplier materials, parts, and services conform to FAA-approved design. For the purpose of this section, the term "supplier" includes distributors.

- Initial and periodic evaluations of suppliers were not made, as necessary, or corrective actions were not taken to correct system deficiencies.
- Receiving inspection failed to verify that supplier-furnished parts/services conformed to FAA-approved design data.
- Suppliers were used that were unapproved by the facility or a system to establish minimum acceptability criteria for suppliers and assess each supplier to that acceptability criteria was not maintained.
- The evaluated facility failed to flow down applicable technical and quality requirements to suppliers, both in the U.S. and in other countries.
- Raw material, including process material (such as weld rod, etc.), was not verified or identified.

Tool and Gauge - The function which establishes control of precision measuring devices (e.g., tools, scales, gauges, fixtures, instruments, or automated measuring machines) used in fabrication, special processing, inspection, and testing of detail parts, assemblies, and completed products to determine conformity to FAA-approved design.

- Tools and gauges were not initially approved or were not periodically inspected and calibrated.

Design Data Control - The planning and integration of the evaluated facility's procedures for continuously maintaining the integrity of design data, as approved by the FAA or FAA-delegated representatives, in the completed product. This includes software used in type-certificated aircraft or related products (airborne software).

- The facility lacked a drawing control system.
- The issuance, retrieval, distribution, and currency of design and technical data was not controlled.
- Minor design changes were not approved under a method acceptable to the FAA. A TSO facility did not submit to the FAA all necessary revised data resulting from a minor change to the TSO article.

Nonconforming Material- The method of controlling, evaluating, and dispositioning of any part/product which does not conform to FAA-approved design.

- Nonconforming parts/products were not identified, controlled, or dispositioned.
- Material dispositioned as scrap was not permanently identified as such or disposed of.

Material Handling/Storage- The methods used to protect raw materials, parts, subassemblies, and completed products during manufacture, inspection, test, storage, and preparation for shipment to prevent damage, deterioration, or contamination.

- Parts/products subject to age control, deterioration, or corrosion from prolonged storage were not identified or controlled.

The above six subsystems have been the most predominant areas for issues since the data was baselined in FY 1995. A more detailed analysis of these trends is presented throughout *Section 3* of the report.

Whereas the various types of manufacturing facilities have issues in the same areas, the FY 1998 analysis is the first year where a difference was indicated in the compliance rates among them. TSO authorization holders appear to have a higher noncompliance rate than the other facility types. Priority part suppliers appear to have the lowest rate of noncompliance of the facility types. PC and PMA holders appear to be similar in their compliance rates. *Section 3.4* provides more detail into the similarities and differences among various manufacturing facilities.

Since FY 1995, the combined factor of facility size and quality system complexity has been demonstrated as a key factor in the number of finding and observations recorded. A small facility with simple systems will, on average, have a better compliance rate than a large facility with complex systems. *Sections 3.4 through 3.7* of this report provide more detail into the similarities and differences among various facilities.

The FY 1998 analysis builds upon the results of the FY 1996 and FY 1997 analyses to provide significantly better insight into the influence internal audit programs have on compliance in areas other than internal audit. Facilities with an internal audit program in place appear to have fewer findings and observations than those facilities without such a program. This disparity in compliance rates is more pronounced for large facilities with complex quality systems. Simply implementing an internal audit program, however, is not sufficient. The internal audit program must be compliant with those procedures that define it. Should the internal audit program be noncompliant with its own procedures, a loss of quality management control can occur within the areas that internal audit is attempting to monitor. Facilities which were found to be in noncompliance with their own internal audit procedures were twice as likely to have systemic issues in one or more of the other sixteen subsystems. Also, those facilities that violated their own internal audit procedures had three times the number of findings and observations than those facilities following their own internal audit policies and procedures. In fact, nearly every facility that was not following its internal audit procedures had additional findings in other areas. Both industry and the FAA should carefully consider the implications of this trend. The analysis and its detailed findings are presented in *Section 3.8*.

The FY 1997 ACSEP analysis results were discussed with industry at the October 1998 meeting between the FAA and the Manufacturing, Maintenance, & Repair Committee (MMRC) of the industry groups Aerospace Industries Association (AIA) and the General Aviation Manufacturers Association (GAMA). Based upon the analysis results, the MMRC agreed to form two teams, in cooperation with the FAA, to attempt to formulate plans to reduce findings and observations. The two areas of focus are supplier control and internal audit. The supplier control team will seek to develop a plan to reduce findings and observations in their supplier control processes. The internal audit team will attempt to define what internal audit programs might entail. The actions of both teams are presently underway and should result in policy development. Further status of the two teams will be reported in next year's report.

A noteworthy revision to the ACSEP program occurred during FY 1998 — the addition of facilities with engineering delegation to the ACSEP evaluation schedule and analysis. FAA Notice N8100.13 was issued incorporating delegated facilities into ACSEP. Delegated facilities include Delegation Option Authorization facilities (DOA), Designated Alteration Stations (DAS), and Special Federal Aviation Regulation No. 36 (SFAR-36) facilities. Delegated facilities were incorporated into ACSEP for the purpose of “determining that the design approval system in place at the delegated facility is producing a safe design and is in compliance with the airworthiness requirements.” The initial analysis of the ACSEP evaluations for the delegated facilities is located in *Section 4*. The detailed listing of issues for the delegated facilities can be found in *Section C2 of Appendix C*.

The continuous improvement initiatives implemented in ACSEP have resulted in a steady reduction in difficulties encountered during ACSEP evaluations over the last five years. Evaluation teams in FY 1998 reported 91 percent fewer problems in interpreting and utilizing the ACSEP order and performing evaluations than in FY 1994. In addition, there has been a simultaneous increase in customer satisfaction with ACSEP evaluations. As part of the ACSEP continuous improvement process, the facility's management is provided with a feedback summary on which to record their assessment of the conduct of the evaluation team. All phases of an ACSEP evaluation are addressed from pre-evaluation notification through post-evaluation review of any findings and/or observations. Less than one percent of the facilities returning a feedback summary in FY 1998 reported dissatisfaction with the conduct of the ACSEP evaluation teams. See *Section 6* for additional information on the continuous improvement program of ACSEP.

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FY 1998 Report

1. Introduction

This report summarizes the results of the Aircraft Certification Systems Evaluation Program (ACSEP) and provides a comprehensive view of the program's results from October 1997 through September 1998. The analysis of the data provides insight into procedural compliance trends within the aviation industry and highlights some specific areas of concern.

Order 8100.7, Aircraft Certification Systems Evaluation Program, was released in its final form in March 1994. Prior to this, a draft version was used to perform the evaluations and to collect data. The final order contained some significant changes in the categorization and interpretation of the individual criteria and the method of recording evaluation results. Therefore, data collected for FY 1994 and earlier is not comparable to the data collected after the revised order was published except in a very general nature.

The FY 1995 ACSEP report is considered the baseline from which all time-related trend analyses are established. With the collection of three years of comparable data, this report is the first to present preliminary trend analysis. It should be noted that due to the short timeframe for which data is available, the trends presented in this report are only preliminary. More comprehensive trend analysis will be presented in future reports as the collection of data to permit reliable analysis is accomplished.

1.1 Report Structure

The report is presented in four sections with *Section 1* providing an introduction and overview of the program status. *Section 2* provides summary conclusions for the data collected during FY 1998. *Section 3* provides a consolidation of the analyses for manufacturing facilities that led to the conclusions presented in *Section 2*. *Section 4* provides the initial analysis of data collected at facilities with engineering delegation. Significant events that occurred during the fiscal year are discussed in *Section 5*. *Section 6* provides the results of the ACSEP improvement effort including feedback from industry, lessons learned, and comments received regarding the ACSEP evaluations. Additionally, there are five appendices providing: a brief history and background of ACSEP; a list of definitions; detailed data regarding the specific findings and observations; a summary of a detailed regression analysis of predictive trend factors based on facility complexity; and an explanation of some of the analysis methods.

1.2 Program Overview of ACSEP

This subsection provides an overview of the ACSEP and a brief history of its growth. The ACSEP was developed as a result of numerous years of experience with Quality Assurance Systems Analysis Review (QASAR) audits and observations made during an interim audit program called “Operation SNAPSHOT”. The most significant differences between QASAR and ACSEP are:

- a) ACSEP evaluations are performed in accordance with consistent and standardized evaluation criteria.
- b) The evaluation criteria used during an ACSEP evaluation were developed with extensive input and cooperation from the aviation industry to ensure that emerging technologies were addressed.
- c) ACSEP evaluation results are maintained in a centralized database that allows statistical trend analysis.
- d) An annual report of the aggregate ACSEP evaluation results is published.
- e) ACSEP actively incorporates the evaluation of priority parts suppliers to the production approval holders. Facilities with engineering delegations are also evaluated. The facilities that are evaluated by ACSEP are:
 - Approved Production Inspection System (APIS)
 - Production Certificate (PC) and Production Certificate Extension (PCEX)
 - Parts Manufacturer Approval (PMA)
 - Technical Standard Order (TSO) authorization
 - Priority Part Suppliers (PPS) to the above production approval holders
 - Delegation Option Authorization (DOA)
 - Designated Alteration Station (DAS)
 - Special Federal Aviation Regulation No. 36 (SFAR-36)

A more detailed history and background of ACSEP, the structure of the evaluation teams, and departmental interactions are discussed in *Appendix A*.

The transition from QASAR to ACSEP occurred in FY 1993. The evaluation of delegated facilities began after the release of Notice N8100.13, Aircraft Certification Systems Evaluation Program Criteria for Delegated Facilities, on July 24, 1997. Since FY1993, the number of evaluations performed each year has increased an average of 24 percent annually. *Figure 1-1* shows the growth of the program from FY 1993 to FY 1998. The growth of the program was facilitated by an increase in the number of qualified manufacturing, engineering, and flight test personnel fully trained to perform ACSEP evaluations. The relatively rapid growth in the number of evaluations performed at facilities outside of the U.S. — from zero international evaluations in FY 1993 to 43 evaluations in FY 1998 — is indicative of the increasing globalization of aviation supplier relationships.

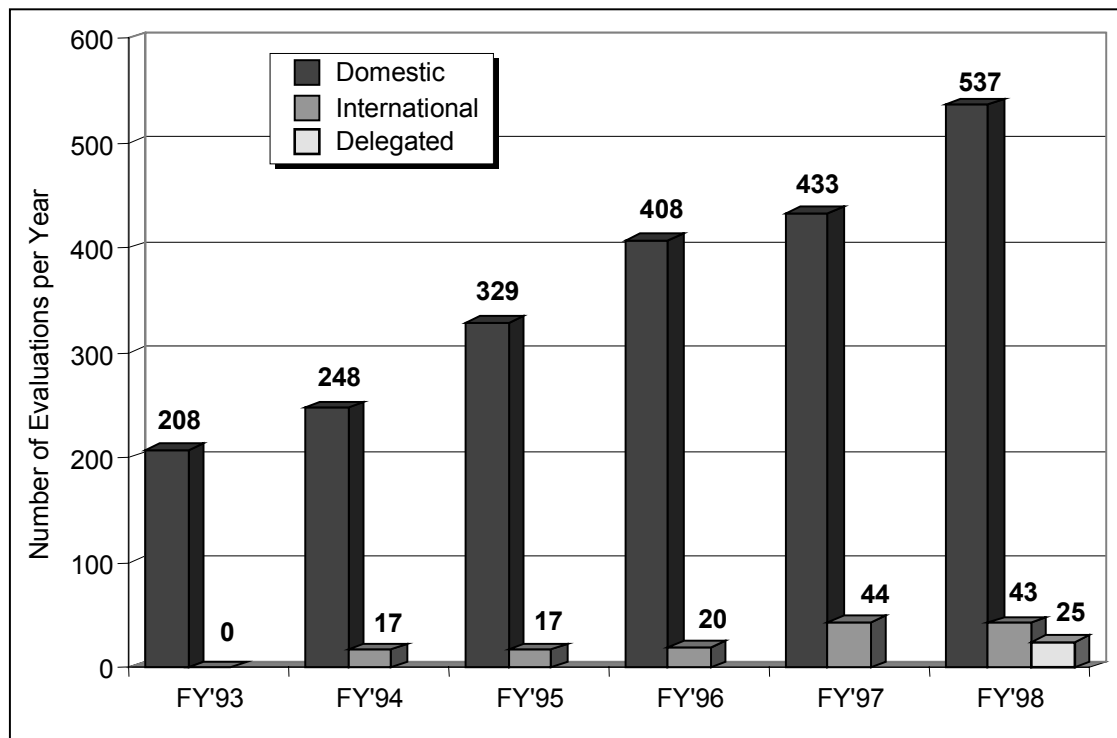


Figure 1-1.—Growth in annual ACSEP evaluations.

Table 1-1 itemizes the population of various production approval holders¹. The growth in the number of manufacturing evaluations among the various facility types is presented in Figure 1-2.

TABLE 1-1.—The population² of PAHs for fiscal years 1993 through 1998

Fiscal Year	Parts Manufacturer Approval (PMA)	Technical Standard Order (TSO) Authorization	Production ³ Certificate (PC)	Approved Production Inspection Systems (APIS)	Total number of Production Approval Holders (PAH)
1993	1,087	367	73	13	1,540
1994	1,140	379	74	14	1,607
1995	1,106	309	88	5	1,508
1996	1,413	342	70	13	1,838
1997	1,437	364	98	8	1,907
1998	1,211	307	98	5	1,621

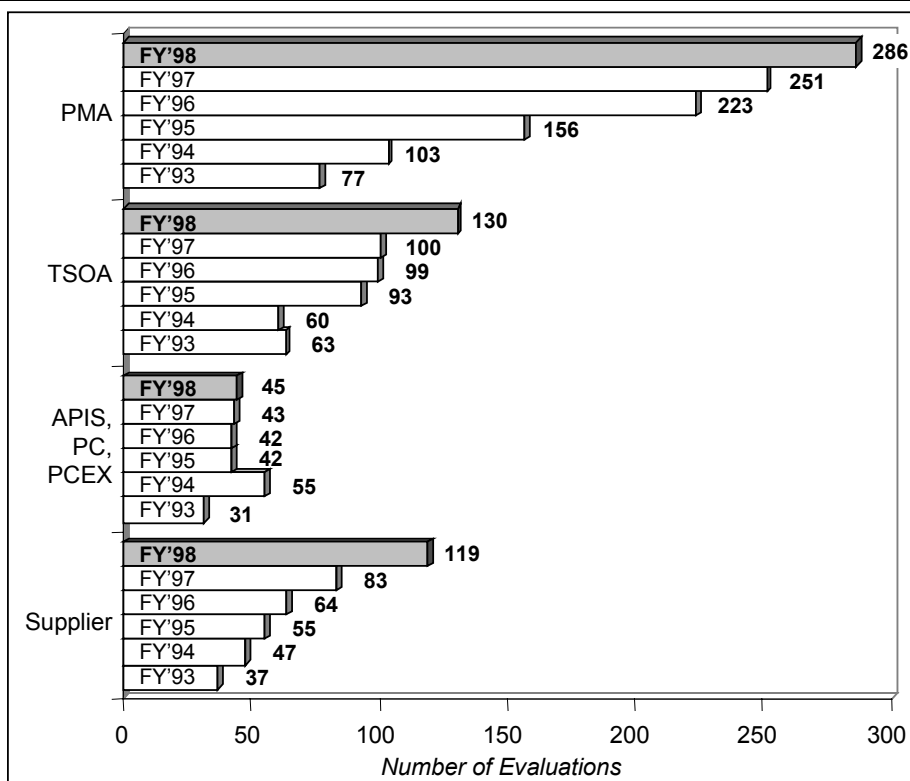


Figure 1-2.—Distribution of ACSEP evaluations at manufacturing facilities by facility type — domestic and international combined.

¹ Facilities with multiple production approvals are accounted for only once in accordance with the following order of precedence: PC (or PCEX), TSOA, APIS, and PMA.

² This table is a compilation of data received from the individual directorates and is included in this report for reference only.

³ Includes PC extensions.

ACSEP evaluations were conducted by the Aircraft Certification Service's four directorates. There were 13 nationally led evaluations headed by a team leader from AIR-200. *Figure 1-3* shows the distribution of all manufacturing evaluations among the four directorates.

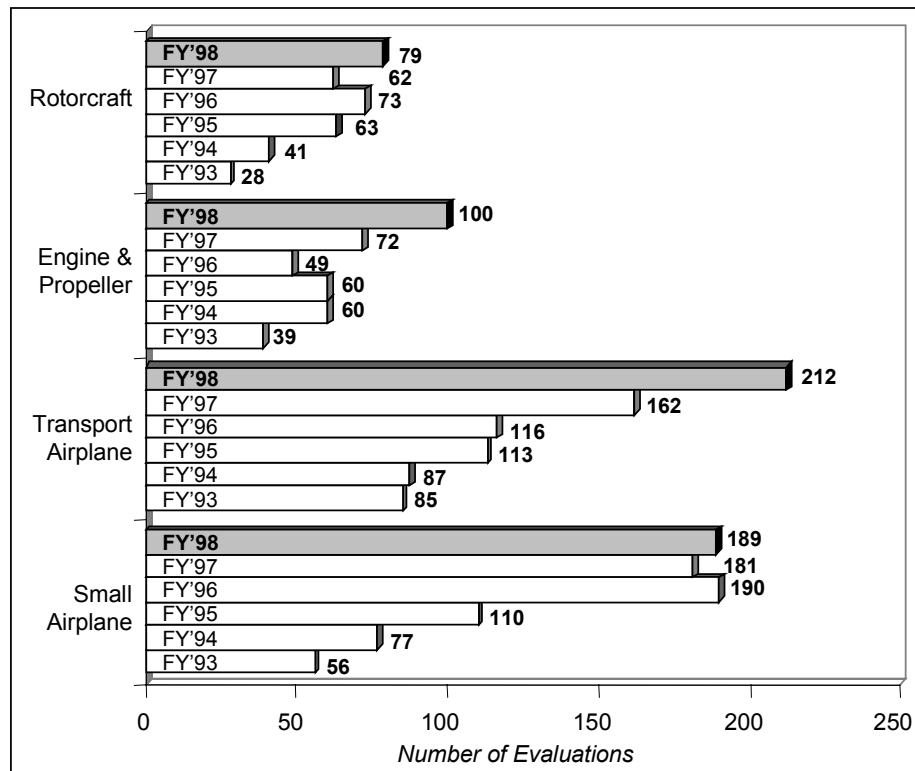


Figure 1-3.—Distribution of ACSEP evaluations at manufacturing facilities by directorate — domestic and international combined.

Table 1-2 lists the population of the various delegations. The distribution of the delegated ACSEP evaluations among the various delegation types and among the various directorates is shown in figures 1-4 and 1-5 respectively.

TABLE 1-2.—The population⁴ of delegated facilities for fiscal 1998

Fiscal Year	Designated Alteration Station (DAS)	Special Federal Aviation Regulation No. 36 to FAR part 121 (SFAR-36)	Delegation Option Authorization (DOA)	Total number of Delegated Facilities
1998	31	24	6	61

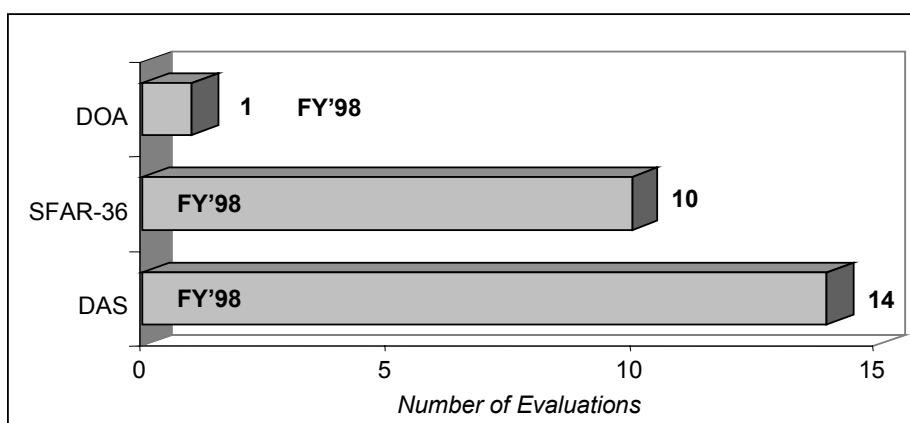


Figure 1-4.—Distribution of ACSEP evaluations at delegated facilities by delegation type.

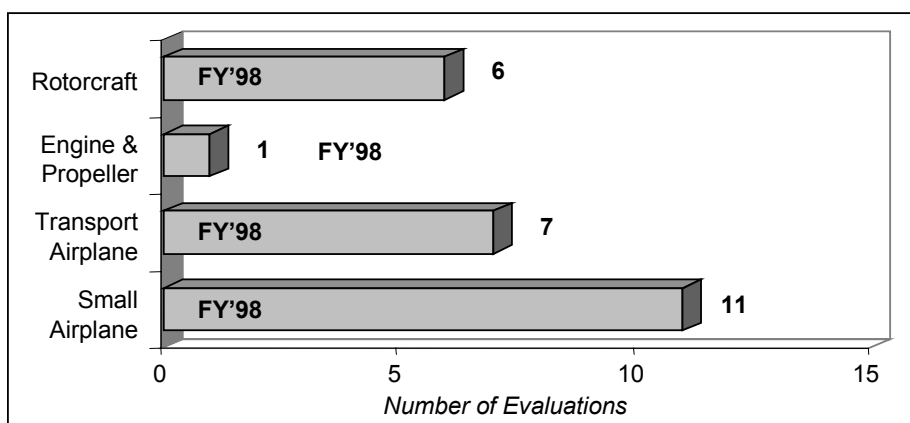


Figure 1-5.—Distribution of ACSEP evaluations at delegated facilities by directorate.

⁴ This table is a compilation of data received from AIR-100 and is included in this report for reference only.

1.3 The Data Collected During an ACSEP Evaluation

The ACSEP was designed to determine if FAA production approval holders, their priority parts suppliers, and delegated facilities are complying with the requirements of applicable Federal Aviation Regulations (FAR) and their procedures established to meet those requirements. It also surveys the application of standardized industry practices not required by the FAR to identify national trends that may require development of new or revised regulations, policy, or guidance. The elements of the evaluation are referred to as criteria. Data is collected on noncompliance, nonconformance, and applicability with respect to those criteria.

During an ACSEP evaluation, the actual operating practices of a facility are compared to the FAR, FAA-approved data, and the facility's internal procedures. Any inconsistency discovered (termed issue in this report) is classified and recorded. An issue is classified by its type and the subsystem under which it is noted. There are five issue types:

Safety Finding - an issue that compromises immediate continued operational safety.

Systemic Finding - an issue that is systemic in nature, i.e., is pervasive, repeatable, or represents a breakdown in the quality management system. For an issue to be categorized a finding, it must also be a noncompliance to a FAR or FAA-approved data (or noncompliances with the procurement instrument when a facility is a supplier).

Systemic Observation - an issue that is systemic in nature and is a noncompliance to facility procedures that are not FAA approved.

Isolated Observation - an issue that is isolated or nonsystemic in nature, i.e., isolated to a particular person and/or timeframe and does not represent a breakdown in the quality management system. For an issue to be categorized an isolated observation, it must also be an isolated noncompliance to a FAR or FAA-approved data (or a noncompliance with the procurement instrument when a facility is a supplier).

FAR-based Observation - the discovery of FAA-approved data that is inconsistent with the FAR.

The second form of classification of an issue is the subsystem under which it is discovered. In total, there are 17 subsystems that represent a quality management system for a production approval holder:

- Organization and Responsibility
- Design Data Control
- Software Quality Assurance
- Manufacturing Processes
- Special Manufacturing Processes
- Statistical Quality Control (SQC)
- Tool and Gauge
- Testing
- Nondestructive Inspection
- Supplier Control
- Nonconforming Material
- Material Handling/Storage
- Airworthiness Determination
- FAR Reporting Requirements
- Internal Audit
- Global Production
- Manufacturing Maintenance Facility

There are 10 system elements that represent a quality management system for a delegated facility:

- Organization and Responsibility
- Design Data Approval
- Testing
- Airworthiness Certification
- Continued Airworthiness
- Project Management
- Design Change Approval
- Conformity Inspection
- FAA Notification
- Audit

Each subsystem is further divided into “criteria.” The criteria were developed with extensive assistance from industry in order to fully represent the detailed areas within each of the subsystems and system elements. A process also exists to identify potential new criteria should the existing criteria not address a particular functional area within a subsystem. The subclassification of issues into the detailed criteria allows the FAA to identify specific areas of concern and allows industry to focus corrective action on these specific areas of concern. For example, the supplier control subsystem is composed of 16 individual criteria. Specific areas of concern that may be identified include: the use of approved suppliers; periodic evaluations of suppliers; flowdown of applicable technical and quality requirements to suppliers; raw material verification; and others.

Through the use of detailed criteria and their relevant subsystem and system elements, quality management systems can be evaluated in a consistent manner. The data is collected and analyzed for trends annually. In FY 1995, the data was baselined so that the effectiveness of any industry actions to address issues previously reported can be detected and measured.

2. Conclusions of Data Analysis

Analysis of the FY 1998 ACSEP evaluation data supports the following conclusions⁵:

- There is little difference in the distribution of systemic findings and systemic observations (see *Section 3.2*). Both issue types are common in that both record systemic issues. They differ only in that a systemic finding records a nonobservance with the FAR, FAA-approved data, or a noncompliance by a supplier with the procurement instrument, whereas a systemic observation records a noncompliance with a procedure that is neither FAR-based nor approved by the FAA. From a data analysis standpoint, findings and systemic observations can be considered as one classification of issues that can be combined when analyzing compliance distributions and trends.
- Systemic issues and isolated issues are also similarly distributed among the subsystems and criteria. Those subsystems and criteria where the most isolated observations were recorded also tended to be the subsystems and criteria where the most systemic issues were recorded. This is consistent with the FY 1995 through FY 1997 analysis. *Section 3.3* provides additional detail on this phenomenon.
- The larger the facility or the more complex the quality management system at the facility (the more parts and products produced, the more processes in place, the more complex the facility's controls, etc.), the higher the probability of findings and observations being recorded. The FY 1995 through FY 1997 analyses also provided strong evidence of the direct relationship between quality management system complexity and the presence of systemic issues. See *Section 3.4* and *Appendix D* for additional information on the relationship between facility complexity and the occurrence of issues.
- The majority of findings and observations are concentrated within a few subsystems: manufacturing processes, supplier control, tool and gauge, design data control, nonconforming material, and material handling/storage (see *Section 3.5*). The issues are also concentrated within a few individual criteria (see *Section 3.6*). In fact, only slightly more than one-half of the criteria had systemic findings or observations recorded against them. The concentration of issues into a select few areas has remained relatively consistent since being first reported in FY 1995.
- The analyses performed FY 1995 through FY 1997 indicated little variance among the various facility types. The FY 1998 analysis, however, indicates a divergence in the

⁵ Due to the low number of international evaluations and correspondingly large prediction error of such a small sample, the conclusions in this report — **unless specifically stated otherwise** — **are based on the results of domestic facilities only.**

compliance rate among some of the facility types. TSO authorization holders had a significantly higher noncompliance rate overall than the other facility types. Whereas, priority part suppliers had significantly fewer compliance issues than any of the other facility types. PC and PMA holders had similar compliance rates. *Section 3.4* provides a detailed discussion on the variances among the facility types.

- Preliminary trend analysis has begun to show some downward trends in compliance issues (see *Section 3.7*). Priority parts suppliers have seen a 24 percent drop in the proportion of facilities with recorded findings and observations. The proportion of PC holders with systemic issues appears to have also dropped slightly, however, not to a significant level as yet. The occurrence of issues at other facility types, overall, remained relatively flat.
- At the subsystem level, five subsystems saw a decrease during the last four years in the percentage of facilities with issues recorded: supplier control, manufacturing processes, design data control, testing, and statistical quality control (SQC). There also appears to be a downward trend in the number of findings and observations recorded for two criteria that have been very prominent over the past four years: initial and periodic evaluations of suppliers (Criteria 10Q1) and control of nonconforming products (Criteria 11Q1). The trend analysis is provided in *Section 3.7*.
- Analysis aimed at uncovering indicators of compliance rates highlighted a very significant area of opportunity. The FY 1998 analysis provides new evidence that implementing an internal audit program reduces findings and observations. This is especially true for larger facilities with complex quality control systems. However, simply implementing an internal audit program was not enough — it is imperative that a facility adheres to its internal audit program. Facilities that did not observe their own internal audit procedures had three times the average number of findings and observations than facilities that were in compliance with their internal audit procedures. *Section 3.8* provides a summary of this analysis.
- International and domestic facilities appear to have similar issues (see *Section 3.9*). The small sample size of international facilities, however, precludes any further assessment of the international facilities.
- This report marks the first year data was analyzed for facilities with engineering delegation. It is too soon for any conclusions to be reached concerning trends. The results of FY 1998 ACSEP evaluations performed on the delegated facilities can be found in *Section 4* and *Appendix C*.

3. Data Analysis — Manufacturing Facilities

3.1 Safety Related Findings

Of the 976 findings and observations recorded in FY 1998, five identified immediate safety concerns. Two of the five safety findings were identified at the same facility. The five safety findings were for:

- Failure to properly inspect a product to ascertain conformance to a specified requirement (Criteria 4Q1).
- Failure of work instructions to control the manufacturing processes (Criteria 4P4) resulting in an unsafe installation condition. A service bulletin was subsequently released to correct the situation.
- Improper utilization of a Special Flight Authorization for customer crew training (Criteria 13Q2). The same facility also failed to properly conduct all in-process inspections prior to final inspection of a product (Criteria 4Q12) resulting in a Airworthiness Directive being issued by the FAA to correct the situation.
- Failure to control and properly document a repair to a nonconforming part (Criteria 11Q1). All affected parts were subsequently recalled and destroyed.

No specific conclusions can be drawn at this time with regard to trends with past safety findings. Future safety findings will continue to be monitored and compared to past safety findings prior to the formulation of any conclusions.

3.2 Systemic Issues (*Findings vs. Systemic Observations*)

A finding records a noncompliance with the FAR, FAA-approved data, or a noncompliance by a supplier with the procurement instrument. A systemic observation records a nonobservance at a PAH to a procedure that is neither FAR-based nor FAA-approved. However, they are similar in that they are both systemic in nature and are both nonobservances to established processes or procedures. In practice, a noncompliance/nonobservance of a procedure can be recorded as either a finding or a systemic observation based solely on whether the procedure was FAA approved. The number of and type of procedures that are FAA-approved varies widely among the facilities. Additionally, the FAR requirements differ among the various facility types. In order to reduce bias, most of the analyses within this report pool finding and systemic observation data. Unless otherwise specified, all future references to “systemic issues” will relate to occurrences of both findings and systemic observations. Additionally, unless specified otherwise, all analyses were performed with pooled finding and systemic observation data.

It is interesting to note, however, that findings and systemic observations are similarly distributed among the various subsystems (see *figures 3-1 through 3-3*). The previous reports also showed a similarity in the distribution of findings and systemic observations.

Note: The charts in this report illustrate two important features of the analysis of the evaluation data. The first is the distribution of the data collected from the facilities evaluated, i.e., the **sample**. The second feature is the ability of the analysis to predict the results anticipated at all of the facilities, including those not evaluated, i.e., the **population**. To illustrate how to interpret the analysis results, refer to *figure 3-1*. At the facilities evaluated in FY 1998, 27 percent of the findings were recorded in the Manufacturing Processes subsystem. We would reasonably anticipate that 23 to 31 percent of the findings that might have been collected at all facilities would be recorded in the Manufacturing Processes subsystem. The bracketed number, ($\pm 4\%$), is the statistical error of making inferences about the whole population based upon the sample analyzed. *Appendix E* contains a detailed explanation of statistical error and the equations and assumptions used in this report.

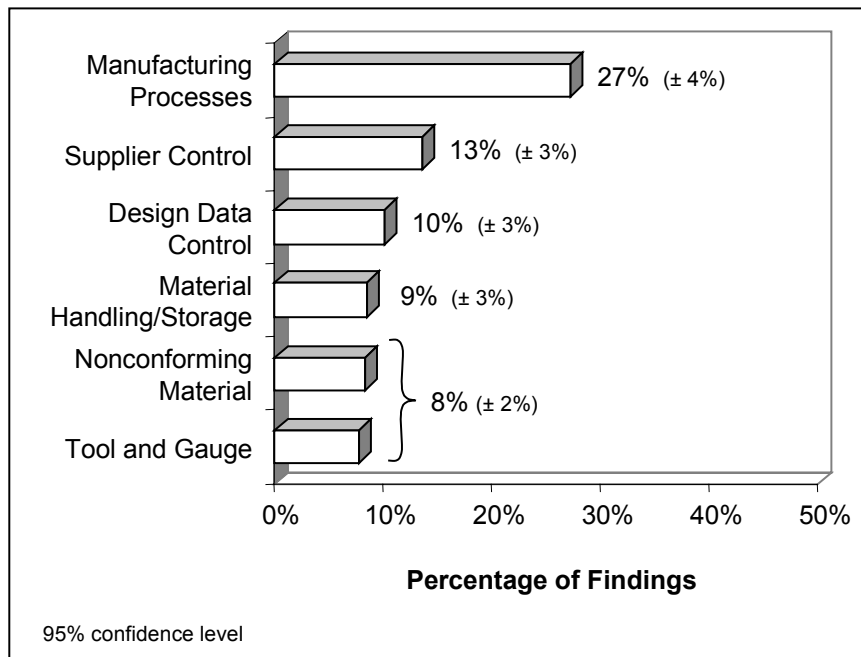


Figure 3-1.—Systemic findings – all facility types⁶.

⁶ Most of the charts presented in this report are plotted with a greater precision than the data labels used to annotate them. Apparent differences between data points equally labeled are due solely to rounding the data label values.

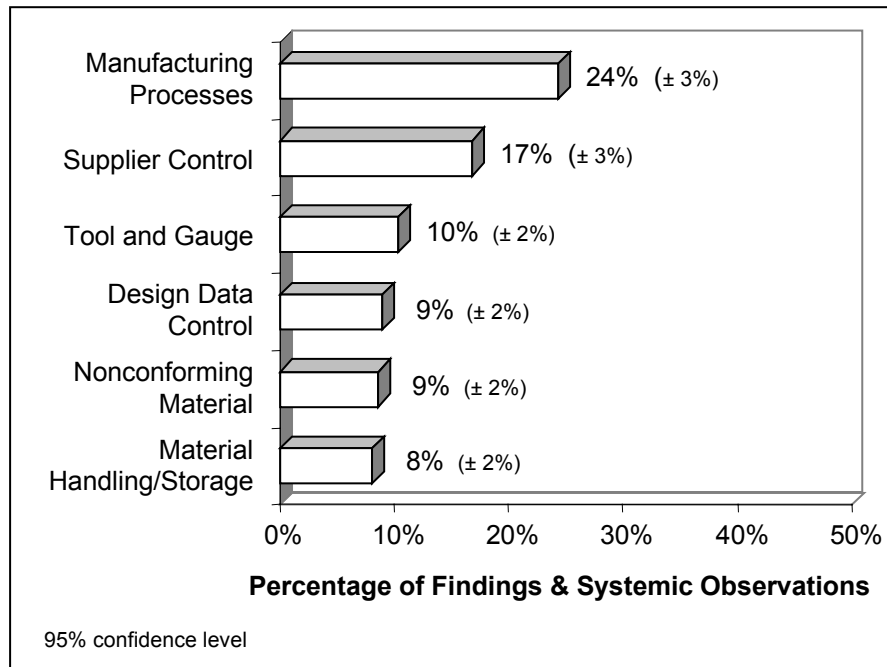


Figure 3-2.—Systemic observations – all facility types.

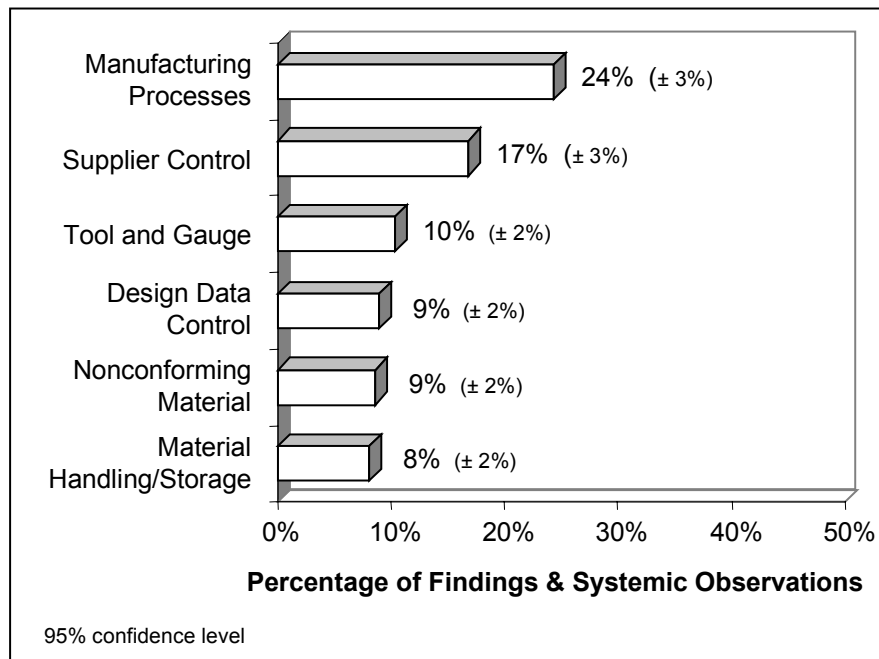


Figure 3-3.—Systemic findings and systemic observations – all facility types.

3.3 Isolated and Systemic Issues

There appears to be similarity between the distribution of systemic issues and the distribution of isolated issues. The differences between the two types of issues are:

Systemic issue	<ul style="list-style-type: none"> • System breakdown • Pervasive • Repeatable • Safety related
Isolated issue	<ul style="list-style-type: none"> • Not a system breakdown • Confined • Random event

Figure 3-4 represents the frequency distribution of isolated observations at the subsystem level. Notwithstanding the reduced rate of occurrence of isolated observations, the frequency distribution of these observations is similar to the distribution of systemic issues (refer to figure 3-3). Table 3-1 compares the top tenth percentile of isolated observations at the criteria level to those criteria with systemic issues also within the top tenth percentile. More than half of the top isolated issues are also the top systemic issues. The correlation between isolated and systemic issues has been seen for the last four years. This apparent similarity between the frequency distributions at both the subsystem and criteria level supports the conclusion that they are somehow related.

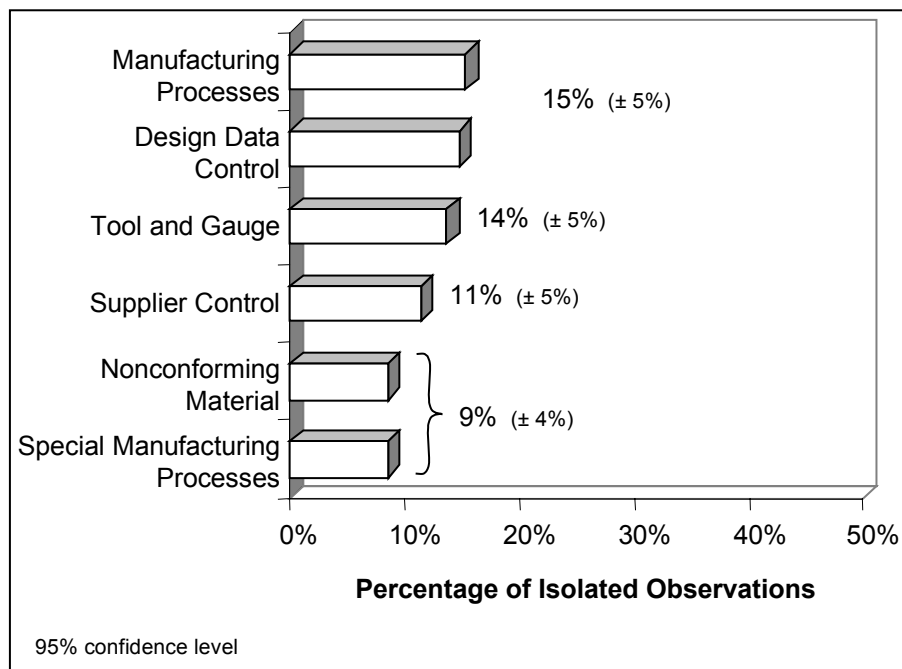


Figure 3-4.—Frequency distribution of isolated observations – all facility types.

TABLE 3-1. —Top ten percentile of isolated issues compared to the top ten percentile of systemic issues

Criteria	Description	Rank of Isolated Observation	Systemic Issues
7Q1	Approval/inspection of tools and gauges	1	✕
2E2	Drawing control system	2	
12Q5	Identification of age control parts	3	✕
11Q2	Permanent identification of scrap material	4	✕
2E7	Design/Technical data control	5	
7Q14	Identification of gauges	6	
5Q2	Processes, equipment, and/or operations qualified and approved	7	
5Q3	Special processes in accordance with established process specifications	7	✕
11Q1	Control of nonconforming products	7	✕
✕ = within top ten percentile of systemic issues			

Assuming the correlation exists, and there is strong evidence from the FY 1995, FY 1996, FY 1997, and the FY 1998 data to suggest that it does, there are two probable causes for this apparent similarity between systemic and isolated issues. One theory is that the distribution of isolated issues follows the natural probability frequency of systemic issues, i.e., those areas that are more prone to systemic issues are also more likely to have isolated issues. Another theory is that a large portion of the isolated issues are indications of larger systemic issues rather than solely isolated issues. In other words, given more investigation, sufficient evidence could have been uncovered to lead the evaluation team to determine the issues to be symptoms of latent systemic breakdowns in the quality management system, thereby warranting them to be reclassified as findings. The occurrence of this phenomenon over the last four years warrants further study into the cause of this apparent correlation between isolated and systemic issues.

No reliable comparison can be made at the criteria level for FAR-based observations due to their relatively rare occurrence, i.e., only 49 recorded in FY 1998.

3.4 Comparison of Facility Types

This section compares the occurrence of issues among the various facility types. However, we need to first consider any affect facility size and complexity may have on the results of this analysis. The next subsection discusses the effect that facility complexity has on the ACSEP evaluation results for individual facility types. The subsequent subsections discuss the particular results for each of the three types of issues: systemic, isolated, and FAR-based.

3.4.1 Complexity of Systems

Both the number of systemic and isolated issues and the probability of a facility having such issues correlate very strongly to the complexity of the systems in use at the facilities being evaluated. The probability of a facility having processes noncompliant with established policies or procedures appears to increase proportionately with system complexity (see *Figure 3-5*). It should be noted, however, that a facility's complexity (or simplicity) does not guarantee the presence or absence of noncompliances. There were several examples of fully compliant large, complex systems, and conversely, several examples of small, simple systems with several noncompliances. Regression analysis techniques⁷ indicate a common factor that can be used to predict this phenomenon. This factor was used to normalize the data for comparisons among the various facilities⁸. This normalization removes the apparent bias produced when comparing, for example, a very large, high-technology PC holder with a small, low-technology supplier. The specific results of the normalized comparisons among the various facility types are discussed in further detail in the following subsections.

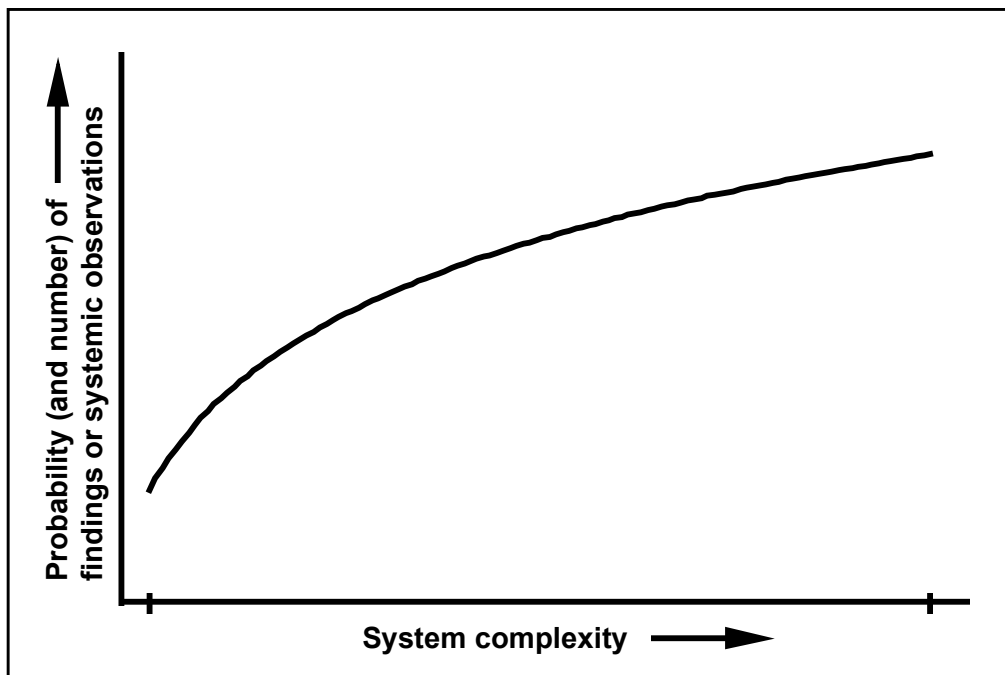


Figure 3-5.—Systemic issues and system complexity are related.

⁷ See *Appendix D* for the details of the regression analysis.

⁸ APIS holders were not included in the normalized analysis because of the large prediction error caused by the small number of data points.

3.4.2 Systemic Issues

The FY 1998 data indicates that the occurrence of systemic issues was relatively similar among PC and PMA holders. TSO authorizations had a slightly higher probability of systemic issues. Priority part suppliers had a significantly lower probability of systemic issues. As a result of the relatively small number of data points associated with using only one fiscal year's data, the error rate is unacceptably high and would tend to mask subtle differences between the facility types. Pooling the FY 1995 through FY 1998 data⁹ yields an overall higher reliability than either of the fiscal year's data alone. The coefficient of dependencies, R^2 , of the pooled data for the individual facility types was over 82 percent, indicating a strong goodness of fit between the trend lines and the actual data. The pooled data also indicates that PC and PMA holders received systemic findings and observations at a similar rate. Priority parts suppliers had systemic issues less often. However, TSO authorization holders had a significantly higher percentage of systemic issues. *Figure 3-6* presents the pooled data normalized for complexity.

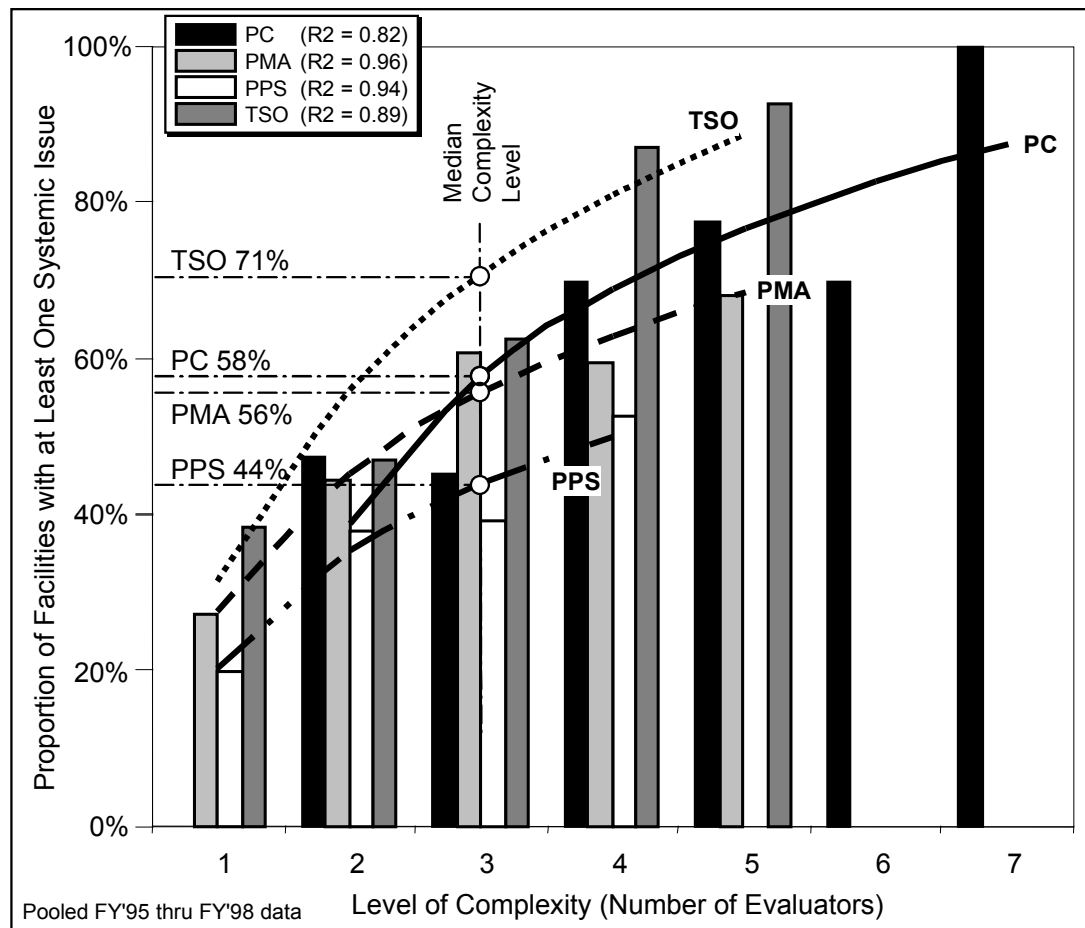


Figure 3-6.—Comparison between the facility types – adjusted for complexity.

⁹ See Appendix E for the justification for pooling the data.

Figure 3-7 presents the same data, but with error bars to highlight the variance in the data¹⁰. For ease of comparison, the median facility complexity of three evaluators per facility was used.

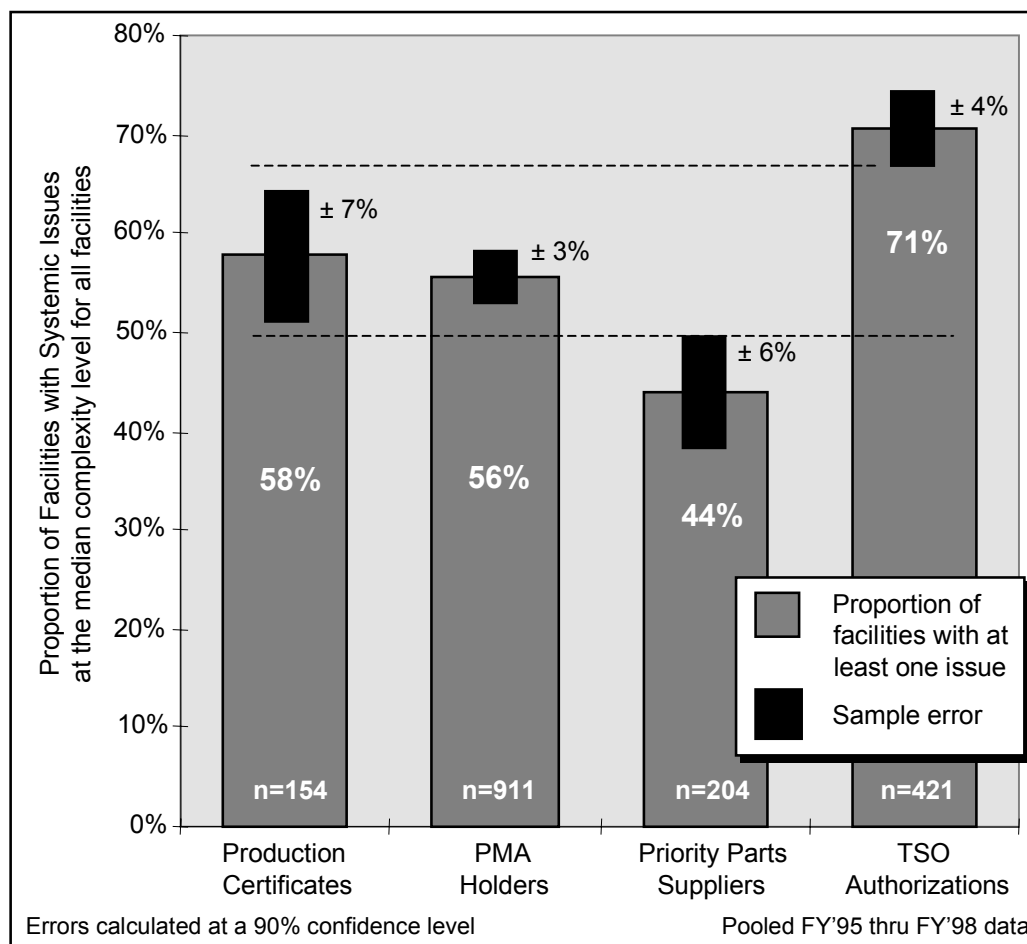


Figure 3-7.—Comparison of the percentages of facilities with at least one systemic issue.

The data presented in figures 3-6 and 3-7 is comparable with the data presented in past reports. An exception to this last statement is the significance of the difference among the facility types due to the increased reliability of the analysis that four years of data provides. The continued downward trend in issues for priority parts suppliers also contributed to the significance of the difference (the trends are discussed in more detail in Section 3.7)

¹⁰ See Appendix E for an explanation of the use of a 90% confidence interval.

A comparison of the normalized data was also made for multiple fiscal years to identify potential trends and to validate the assumption that pooling the data is appropriate. There was little change in the percentage of PMA holders and TSO authorizations with issues from FY 1995 to FY 1998. Therefore, the FY 1995 through FY 1998 data for these two facility types is considered to be from a stable population and appropriate for pooling.

PC holders with systemic issues dropped significantly from FY 1995 to FY 1996, subsequently rose in FY 1997, and dropped slightly in FY 1998. *Figure 3-8* illustrates the fluctuation in the proportion of PC holders with systemic issues over the four years. The FY 1996 report introduced the theory that the drop in the proportion of PC holders with issues was caused by facility selection bias introduced in the initial scheduling of ACSEP evaluations. The biannual cycle in systemic issues for PC holders appears to be smoothing, but still continuing. Since the cycle repeats every two years, the pooling of

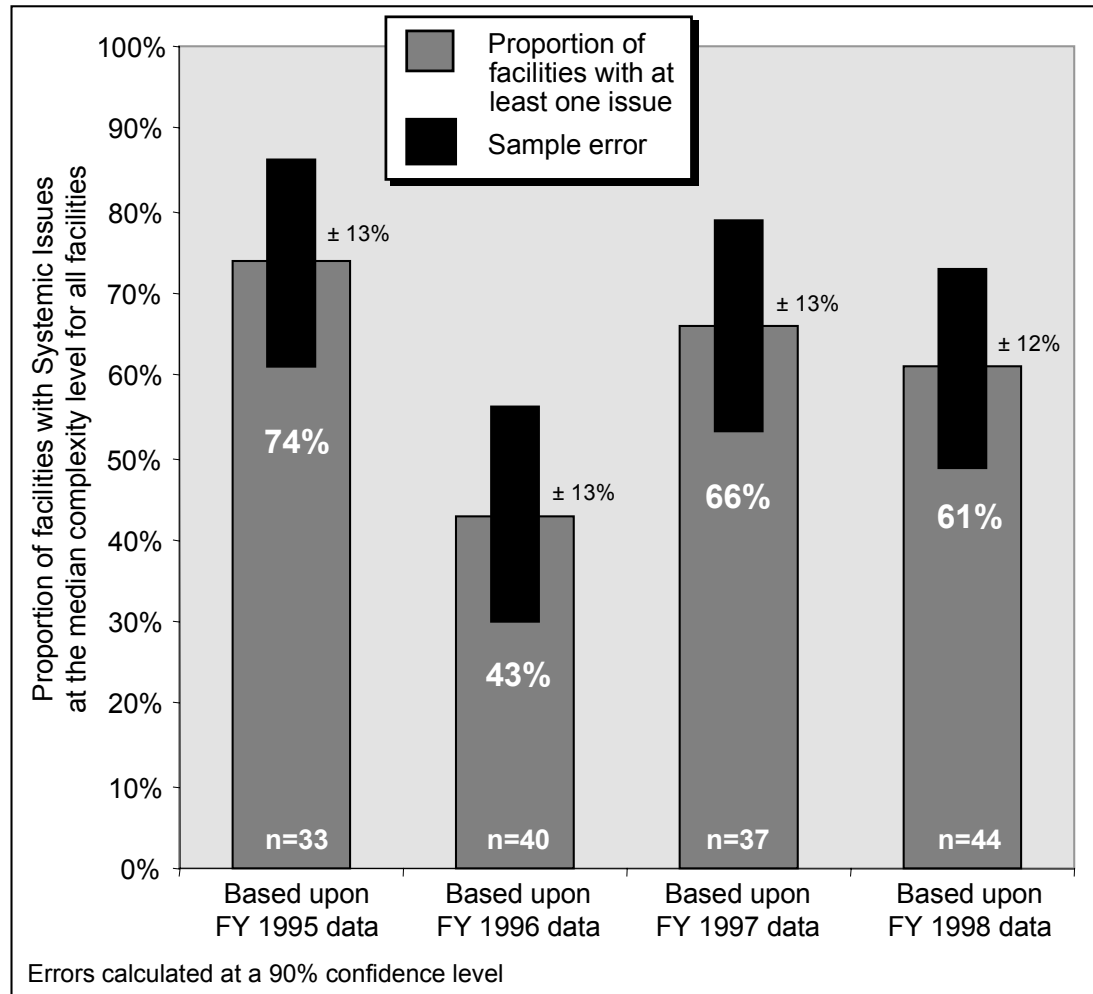


Figure 3-8.—Cyclical change in the percentage of PC holders with systemic issues from FY 1995 to FY 1998.

four years of data is not only considered appropriate under these circumstances, it is a means of compensating for a biannual, cyclical variation in the data.

The four-year analysis also suggests the possibility of a downward trend in the percentage of priority parts suppliers with systemic issues. *Figure 3-9* displays the apparent downward tendency in the probability of systemic issues at priority parts suppliers. The pooled data is considered to be from a downward trend. The frequency of systemic issues currently recorded at priority parts suppliers may be less than the last few percentages suggest. Additional discussion on the trends of the last four years of data is provided in *Section 3.7*.

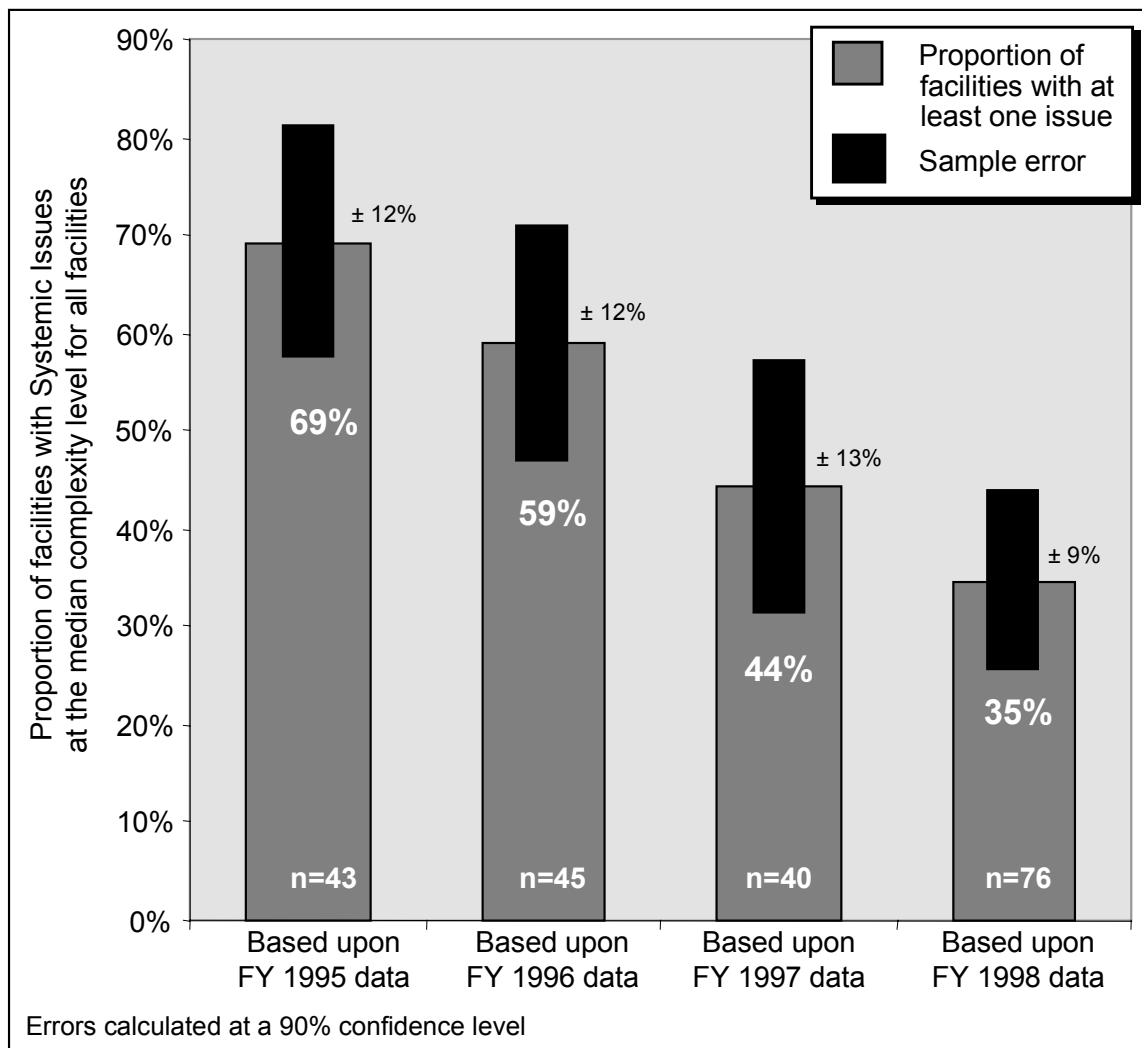


Figure 3-9.—Reduction in percentage of priority parts suppliers with systemic issues from FY 1995 to FY 1998.

3.4.3 Isolated Observations

The same type of analysis as presented in the previous subsection was also performed for isolated observations. The analysis of FY 1998 data indicates that isolated observations are relatively equivalent among the different facility types, except that slightly fewer PMA facilities had isolated observations than the rest of the facility types. There is, however, a relatively high sample error associated with the analysis of any one fiscal year's data. Pooling four years of data drops the error rate to an acceptable range. The analysis of FY 1995 through FY 1998 pooled data indicates that all facility types are similar. Notwithstanding, TSO authorization holders appear to have marginally higher isolated observations and PMA holders had marginally fewer. For clarity, only the analysis of the pooled data at the median complexity level of three evaluators per facility is shown in *figure 3-10*.

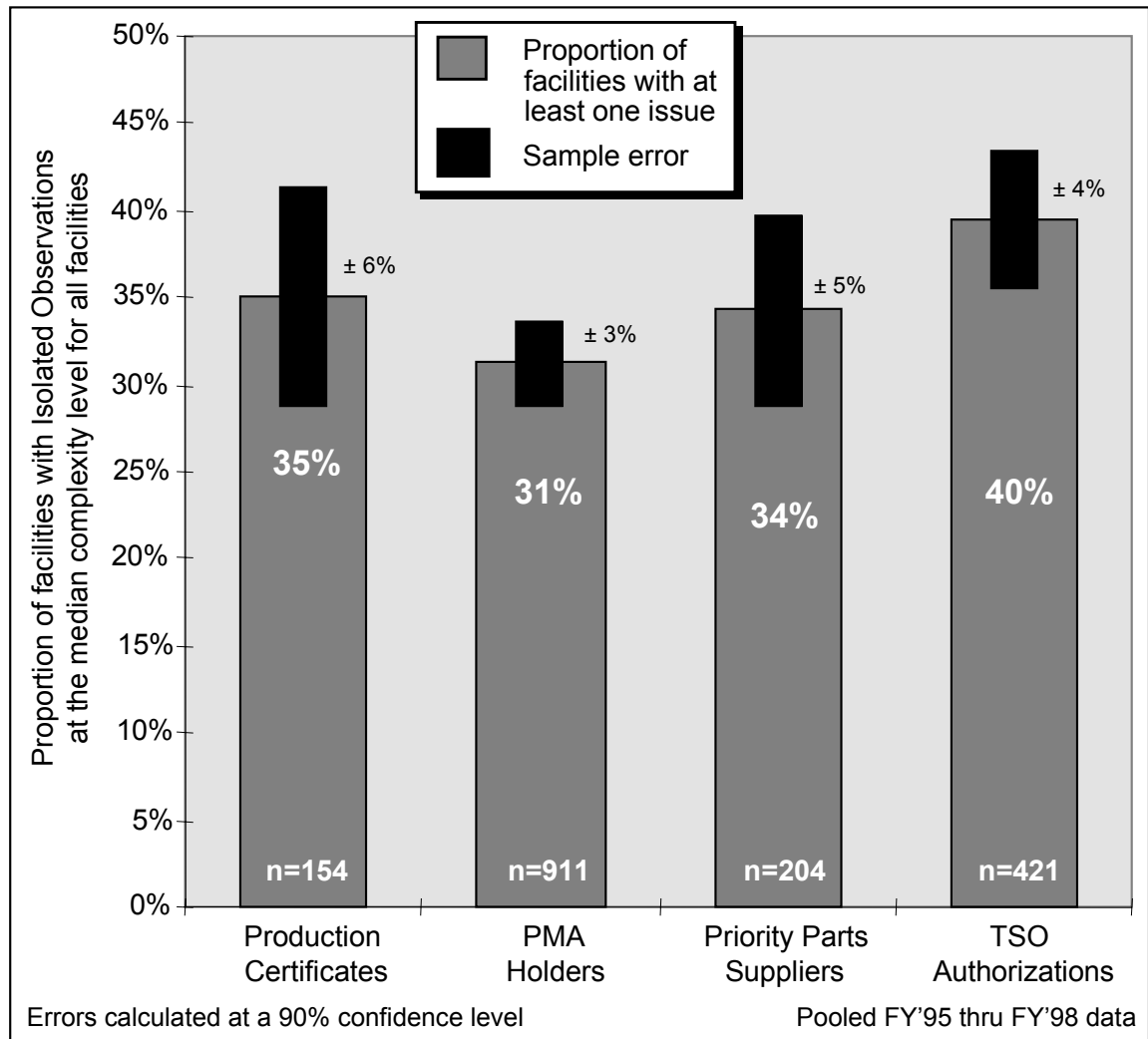


Figure 3-10.—Comparison of isolated observation rate for the various facility types.

3.4.4 FAR-based Observations

The analysis of FY 1998 data for FAR-based observations was similar to previous years. The pooled FY 1995 through FY 1998 data indicates that PMA holders have a lower probability of FAR-based observations than either TSO authorizations or PC holders. For clarity, only the pooled analysis at the median complexity level of three evaluators per facility is shown in *figure 3-11*.

The FY 1995 through FY 1998 data indicates that more than 80 percent of all FAR-based observations were for TSO authorization holders and PMA facilities, 40 percent and 44 percent respectively. PC holders were issued only 14 percent of the FAR-based observations, and only 1 percent were issued to APIS holders.

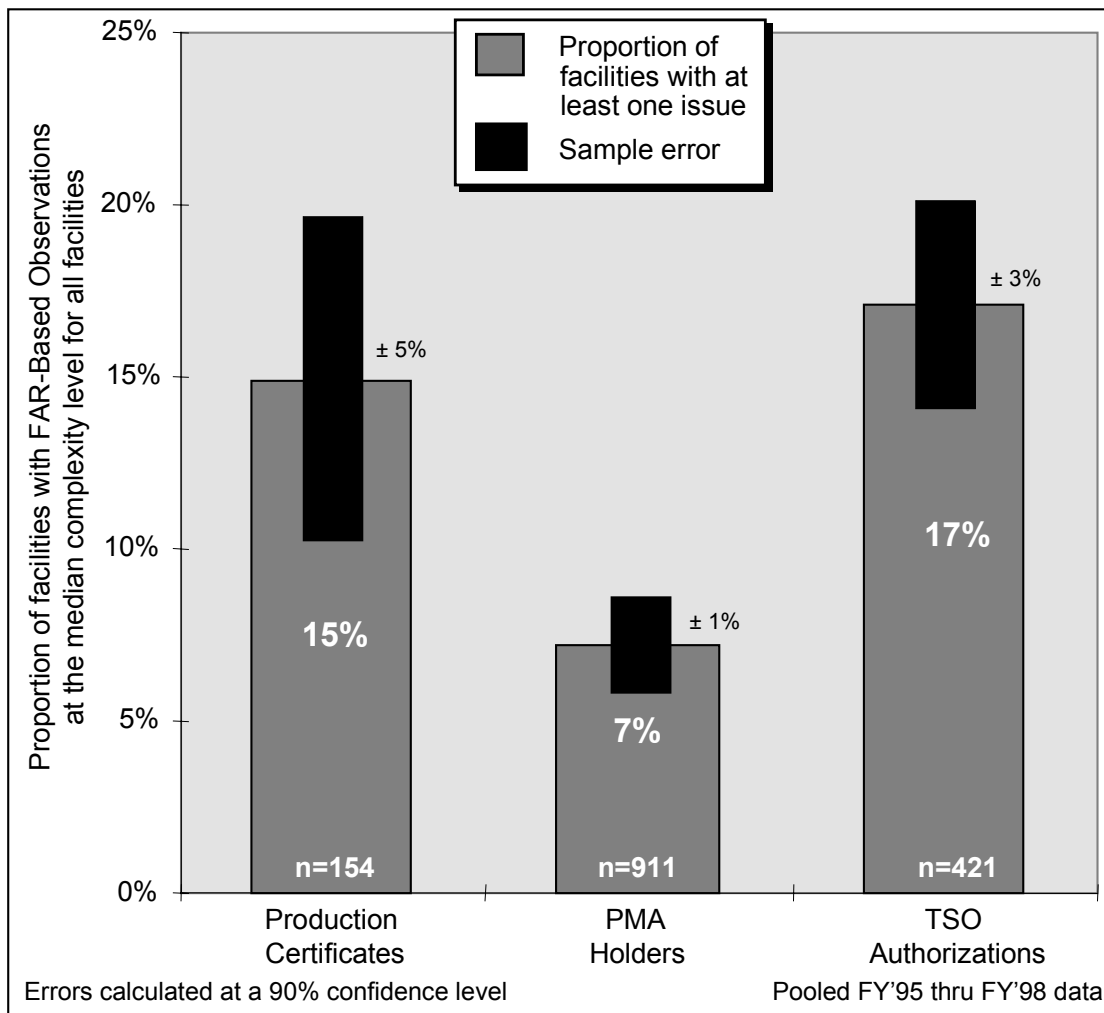


Figure 3-11.—Comparison of FAR-based observation rate for the various facility types.

3.5 Subsystem Issues

3.5.1 Similarity Among Facility Types

The detailed analysis reveals striking similarities in the order in which the facilities have systemic issues within the subsystems. *Figures 3-12 through 3-16* show the most prevalent issues for each of the facility types. *Figure 3-17* shows the most prevalent issues for all of the facility types combined. It is apparent from this analysis that the results for all of the facilities combined also statistically represents the results for any individual facility type. (The few exceptions to this are discussed in the following subsection.) *Table 3-2* summarizes the data contained in the figures by comparing the most prevalent issues among the various facility types.

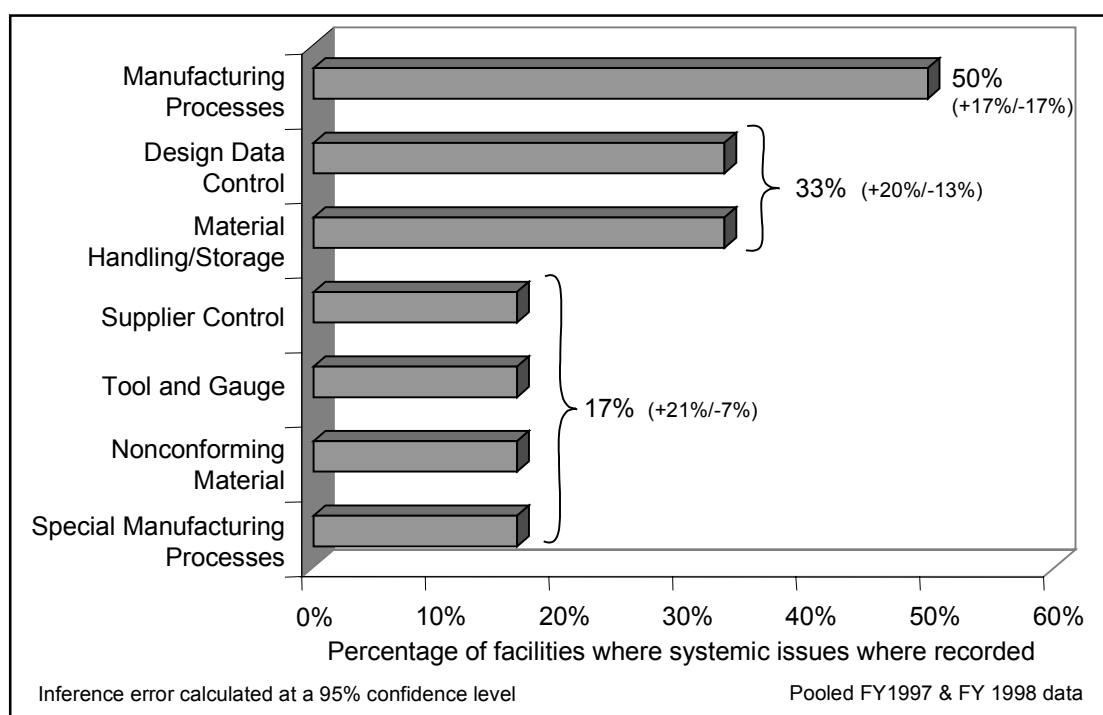


Figure 3-12.—Systemic issues – APIS¹¹ holders.

¹¹ The APIS data is shown with FY 1997 and FY 1998 pooled. No facility was evaluated more than once during this period. Five facilities were evaluated in FY 1997 and only one in FY 1998. The apparently large inferential errors are due to the small number of facilities evaluated. However, the pattern of compliance rates still appears to mirror that of the rest of the industry. See the note in the beginning of this section and *Appendix E* for an explanation of inferential error and its application.

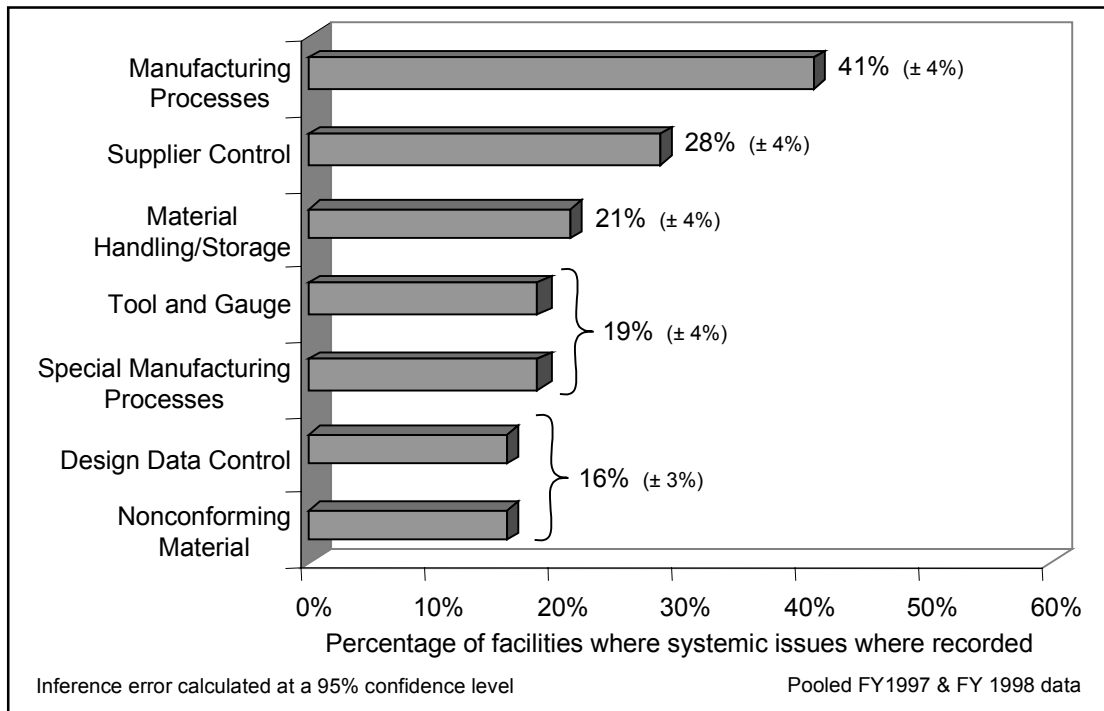


Figure 3-13.—Systemic issues – PC holders.

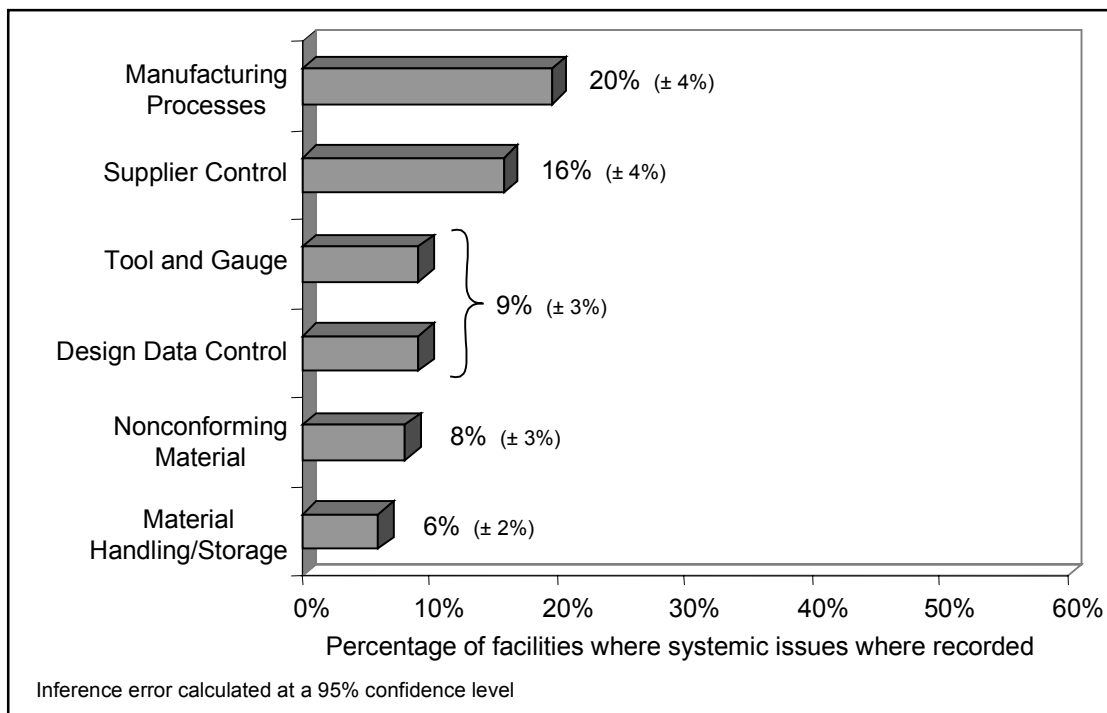


Figure 3-14.—Systemic issues – PMA holders.

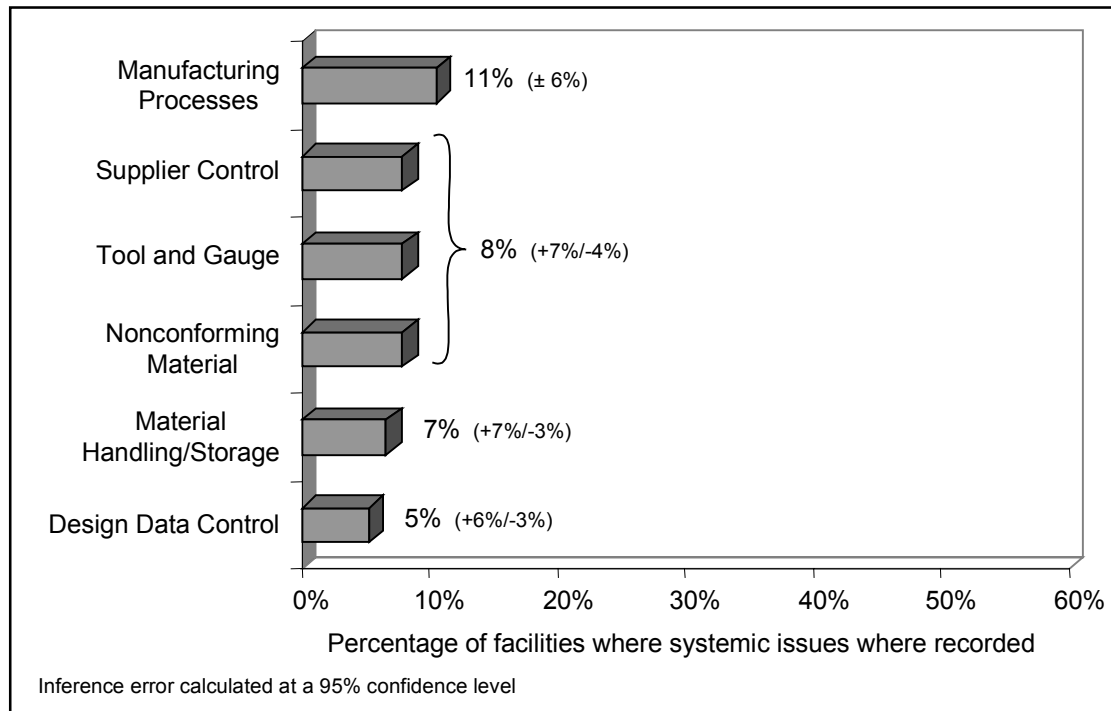


Figure 3-15.—Systemic issues – priority parts suppliers.

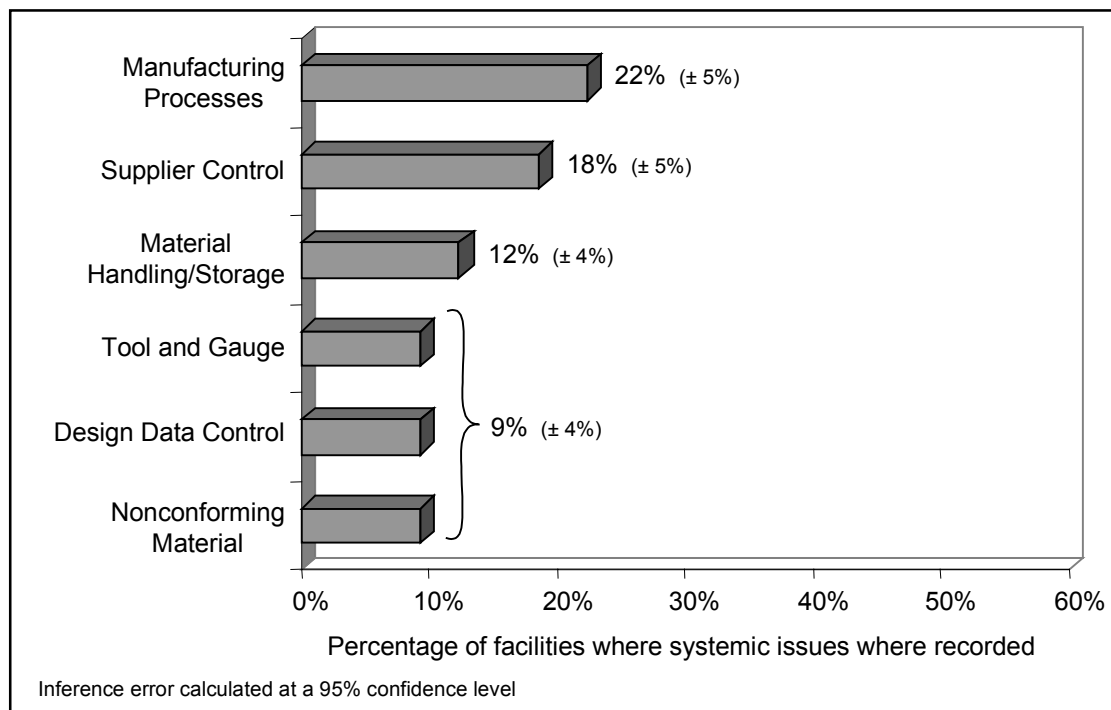


Figure 3-16.—Systemic issues – TSO authorization holders.

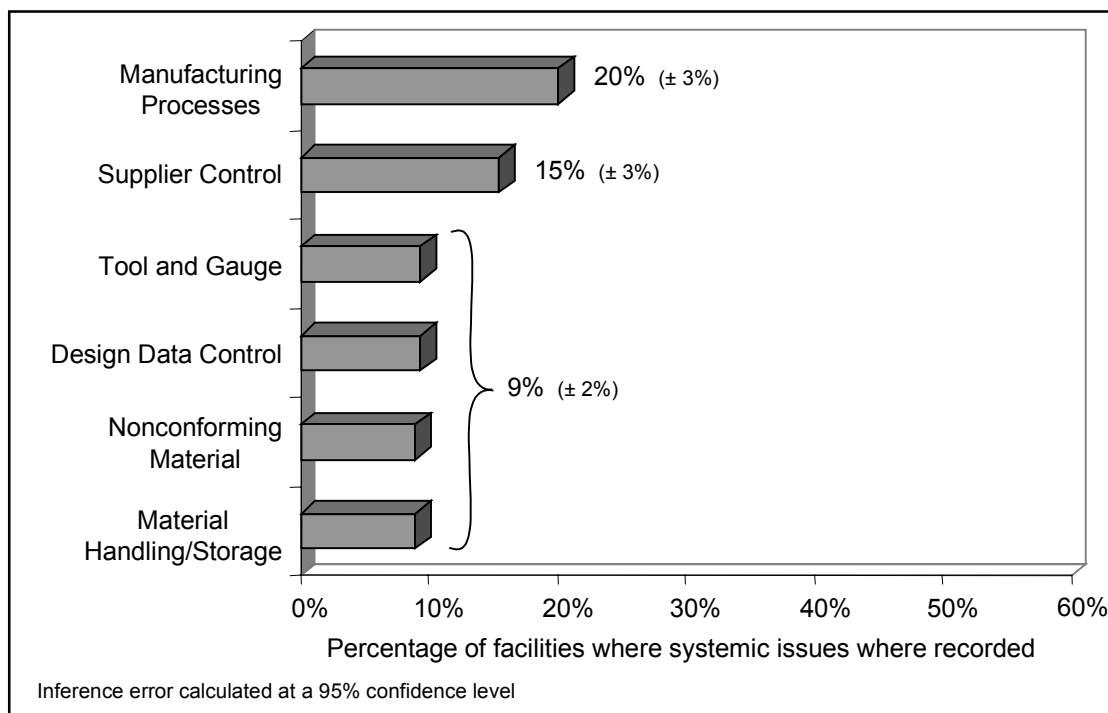


Figure 3-17.—Systemic issues – all facility types.

TABLE 3-2.—Summary of the most prevalent systemic issues

Subsystem	APIS	PC	PMA	PPS	TSO
Manufacturing Processes	✕	✕	✕	✕	✕
Supplier Control	✕	✕	✕	✕	✕
Tool & Gauge		✕	✕	✕	✕
Design Data Control	✕	✕ *	✕	✕ *	✕
Nonconforming Material		✕ *	✕		✕
Material Handling/Storage	✕	✕	✕	✕	✕
Special Manufacturing Processes		✕			
Nondestructive Inspection				✕ *	

Leading issues for the industry

✕ = One of the top six systemic issues

* = Tied

A four-year comparison of the most frequently cited subsystems with systemic issues (see Table 3-3) indicates that there have been only minor variations in the order of occurrence at the subsystem. The various types of facilities appear to have similar key issues. With the exception of some minor shifting in position, the top issues have remained the top issues over the four years.

TABLE 3-3.—Most frequently cited subsystems with systemic issues –
FY 1995 to FY 1998

	Annual Subsystem Rank			
	FY 1995	FY 1996	FY 1997	FY 1998
ALL FACILITY TYPES				
Manufacturing Process	1	1	1	1
Supplier Control	2	2	2	2
Tool and Gauge	4	3	3	3
Design Data Control	3	4	4	3
Nonconforming Material	4	5	6	5
Material Handling/Storage	6	6	4	5
PC				
Manufacturing Process	1	2	1	1
Supplier Control	2	3	2	2
Tool and Gauge	3	1	3	4
Material Handling/Storage	4	8	4	3
Design Data Control	4	5	6	5
PMA				
Manufacturing Process	1	2	1	1
Supplier Control	2	1	2	2
Tool and Gauge	6	4	4	3
Nonconforming Material	4	3	3	5
Design Data Control	3	4	5	3
PPS				
Manufacturing Process	1	1	1	1
Supplier Control	3	2	2	2
Design Data Control	5	3	3	6
Tool and Gauge	2	5	7	2
Nonconforming Material	4	6	6	2
TSO				
Manufacturing Process	1	1	1	1
Supplier Control	1	2	2	2
Design Data Control	3	3	4	4
Tool and Gauge	6	4	3	4
Material Handling and Storage	6	5	9	3

3.5.2 Areas of Significant Difference Among Facility Types

There were four occasions in which there were significant¹² dissimilarities, at the subsystem level, among the various facility types regarding the proportion of facilities with systemic issues. They are, in order of precedence:

Facility Type	Subsystem	Description of Divergence
PC Holders	FAA Reporting Requirements	PC holders had a <u>significantly higher</u> proportion of facilities with systemic issues in the FAA reporting requirements subsystem than the other facility types.
PC Holders	Special Manufacturing Processes	PC holders had a <u>significantly higher</u> proportion of facilities with systemic issues in the special manufacturing processes subsystem than the other facility types.
PC Holders	Material Handling/Storage	PC holders had a <u>significantly higher</u> proportion of facilities with systemic issues in the material handling/storage subsystem than the other facility types.
PC Holders	Testing	PC holders had a <u>significantly higher</u> proportion of facilities with systemic issues in the testing subsystem than the other facility types.

Please note that the above analysis does not take facility size and complexity into consideration. As stated in *Section 3.4.1*, facility size and complexity appear to affect the occurrence of systemic issues. The elevated proportion of PC holders with systemic issues within the subsystems listed above could be solely attributable to the fact that PC holders overall tend to be larger and more complex than the other facility types. There is insufficient data at this time to eliminate facility complexity as a bias from the above analysis. The reader is therefore cautioned to bear this in mind when interpreting the above information.

3.5.3 Facility Perspective

Figures 3-18 through 3-21 compare the probability of facilities having systemic issues before and after adjustment for a subsystem's applicability to the facilities. The earlier charts (*Subsection 3.5.1*) presented the data from an industry perspective. By contrast, the figures in this subsection are more germane to the individual facility types. By adjusting for the applicability of the subsystems within a facility type, subsystems that do not have a wide deployment within a particular facility type increase in their significance.

¹² 95 percent confidence level.

The gray bars on figures 3-18 through 3-21 present the same data as the gray bars on figures 3-12 through 3-16 — the percentage of all facilities with systemic issues recorded. That is, the gray bars show the number of facilities within the facility type with systemic issues divided by the number of facilities evaluated within that facility type. The white bars in figures 3-18 through 3-21 represent the probability of issues at only those facilities in which the subsystems applied. That is, the white bars show the number of facilities within the facility type with systemic issues divided by the number of facilities evaluated within that facility type where the subsystem was found to be applicable. As an example of how this data can be interpreted, we will explore the probability of facilities having systemic issues within the software quality assurance subsystem. Referring to the figures presented in *Subsection 3.5.1* (figures 3-12 through 3-16), the software quality assurance subsystem did not have enough findings or systemic observations recorded for the year to be considered a top issue for any of the facility types. Therefore, the software quality assurance subsystem does not appear on any of the charts presented in *Subsection 3.5.1*. However, in reviewing figures 3-18, 3-19, and 3-21, software quality assurance becomes a significant area for systemic issues. Looking at PC holders, for example, (figure 3-18) only 6 percent of all PC holders had an issue with software quality assurance (represented by the gray bar). However, those PC holders that had software quality assurance systems in place had a 19 percent chance of having systemic issues with those software quality assurance systems (represented by the white bar). This type of presentation of the data allows the reader to focus on those issues relevant to a particular facility with a particular set of capabilities.

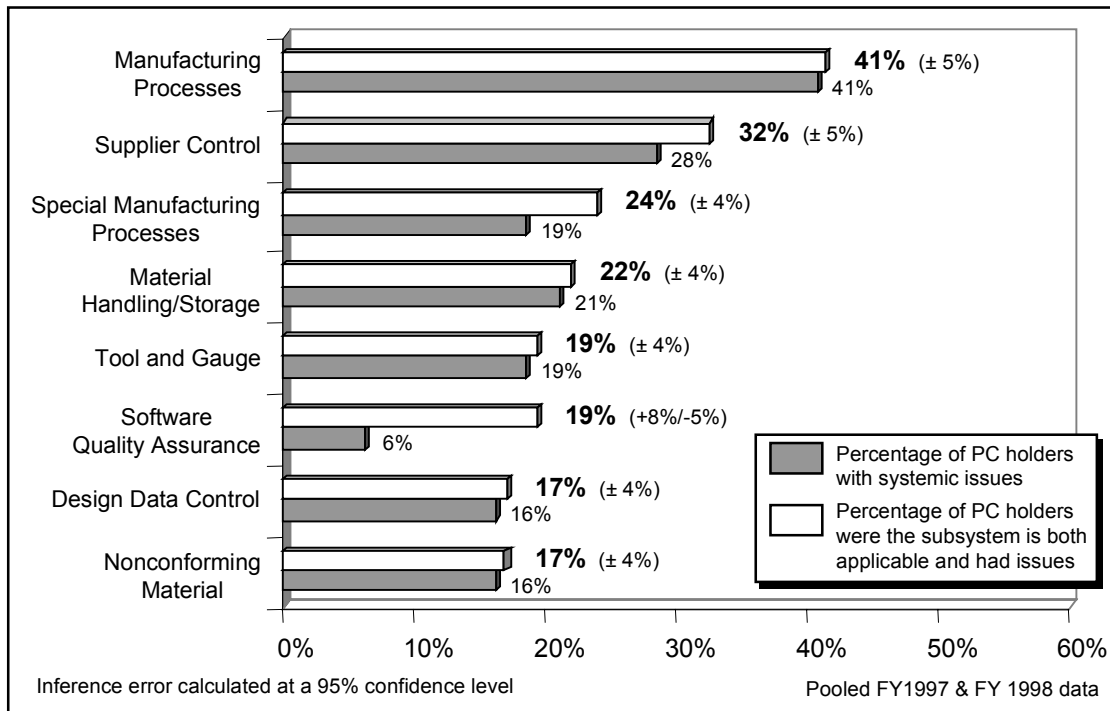


Figure 3-18.—Systemic issues at PC holders adjusted for applicability.

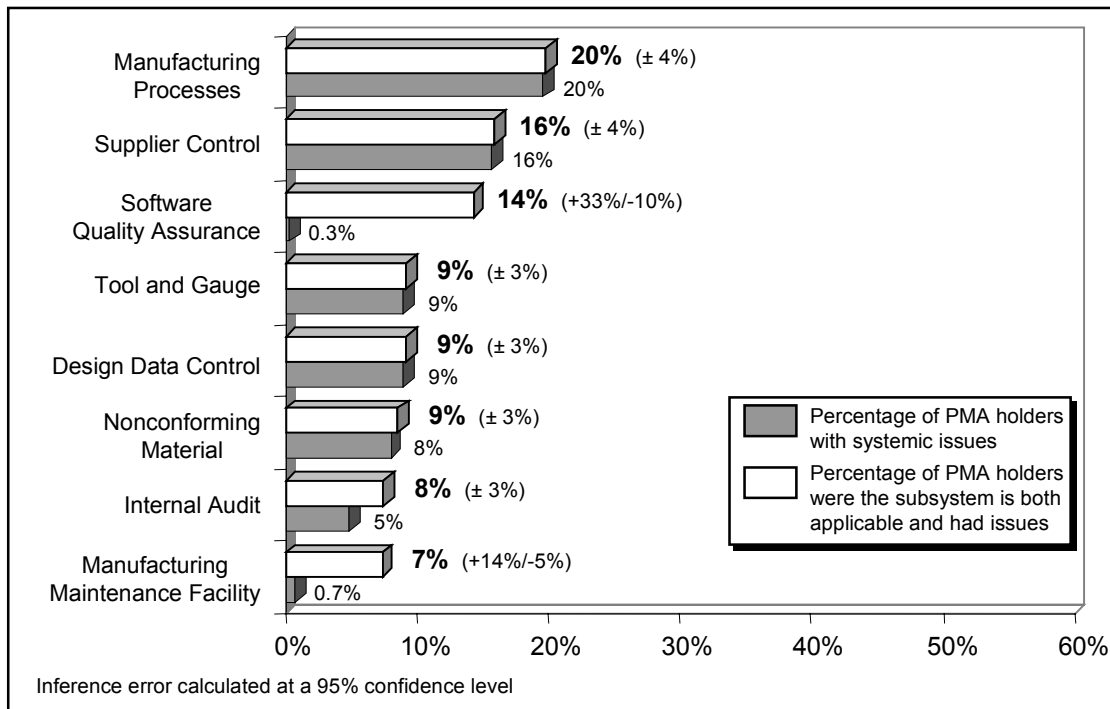


Figure 3-19.—Systemic issues at PMA holders adjusted for applicability.

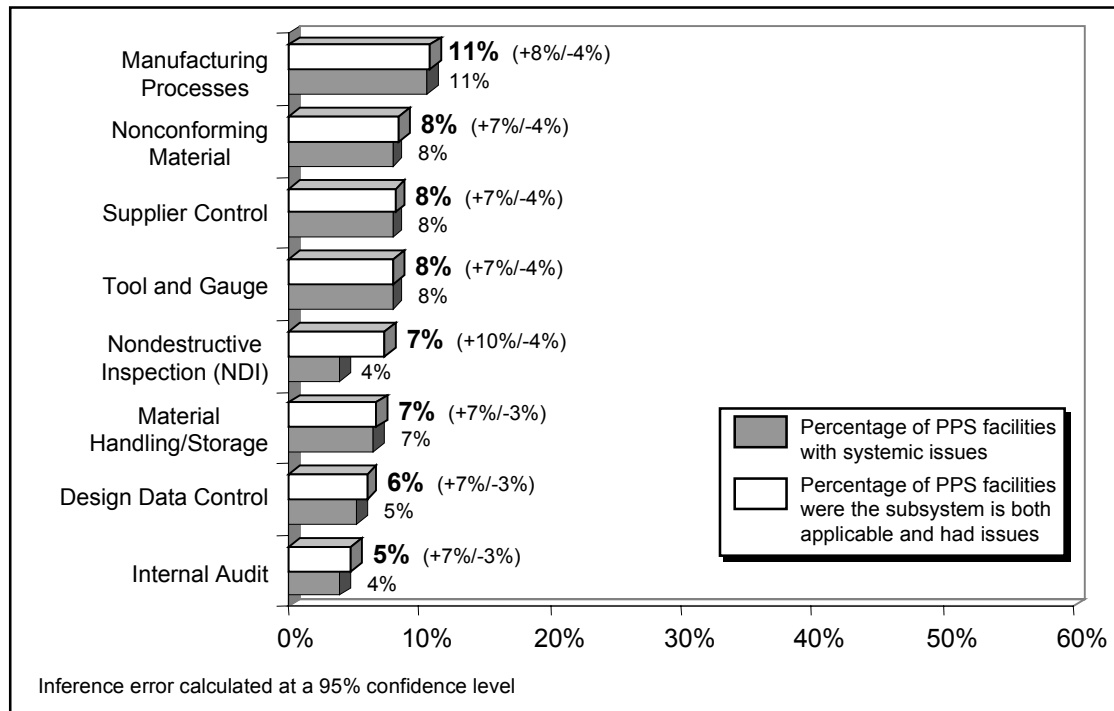


Figure 3-20.—Systemic issues at priority parts suppliers adjusted for applicability.

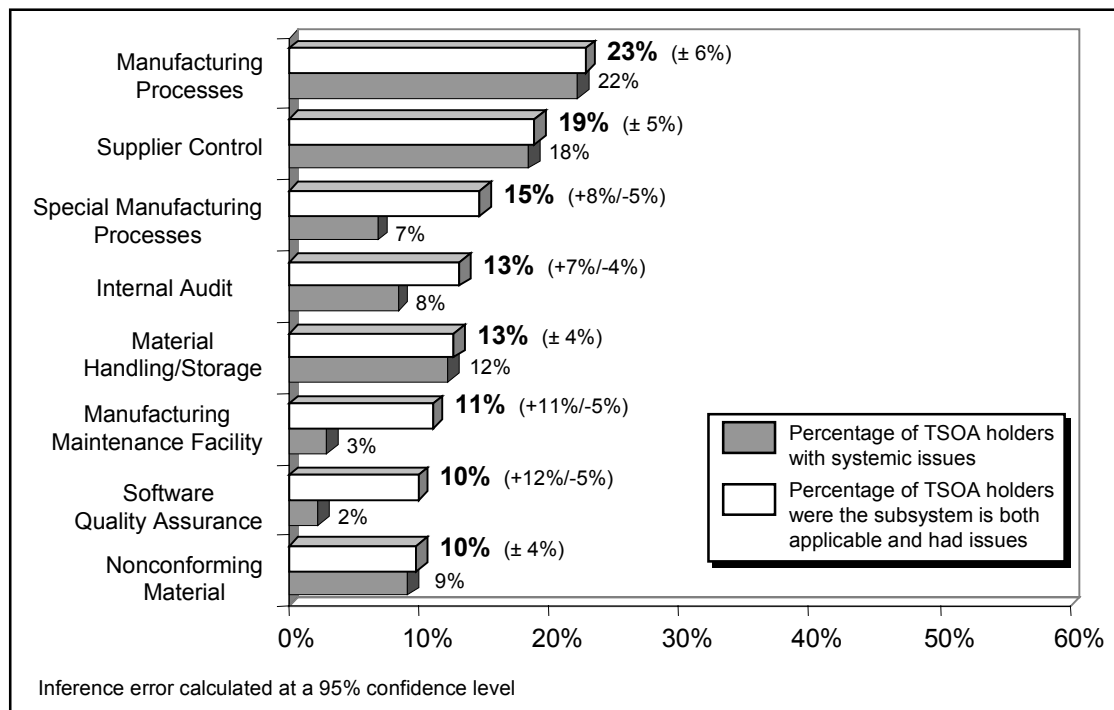


Figure 3-21.—Systemic issues at TSO authorization holders adjusted for applicability.

3.6 Analysis of Evaluation Criteria

The following subsections contain lists of the most significant criteria issues at any given facility type. This data can be used by industry to focus corrective action and by the FAA for resource allocation initiatives. The data is presented in three forms: a view of the industry as a whole listed by type of issue — systemic, isolated, or FAR-based; a focus on individual facility types in which systemic issues are separated by facility type; and a summary of comparisons among the facility types. For clarity, only the top issues are reported in these subsections; however, a full listing of this data can be found in *Appendix C*.

Many of the criteria that are the most prevalent for FY 1998 were also the most prevalent issues reported in the past. *Tables 3-5 and 3-7* present comparisons of the most prevalent criteria with which systemic and isolated issues occurred over the four-year period. The comparisons are done at the industry level only, i.e., with all facility types combined. With 227 different criteria from which to categorize the various findings and observations, a dilution effect occurs as the data is compared at the criteria level. Dividing the findings and observations still further into facility types reduces their occurrence within the individual criteria to a level too low with which to make reliable comparisons. The lowest level these types of comparisons can be reliably made is at the industry level. A four-year comparison of FAR-based observations is not presented due to their rarity, making such a comparison unrealistic.

3.6.1 A View of the Industry

This subsection lists the most prevalent criteria issues within the industry as a whole. The data from all of the ACSEP evaluations performed in FY 1998 are pooled together. The table column titled “Percent of Domestic Facilities” presents the proportion of facilities evaluated that had findings and/or observations recorded. This presentation of the data is similar to that in *Subsection 3.5.1*, i.e., an analysis of the data with an industry perspective. The column titled “Percent of Applicable Facilities with Issues” provides the frequency of findings and/or observations reported at those facilities where the criteria was implemented. This type of presentation of the data is similar to that made for the subsystems in *Subsection 3.5.3*. As an example of this type of data, refer to the fourth row of *Table 3-4* (Criteria 12Q5). This row indicates that 27 systemic issues were recorded for this criteria in FY 1998 – four percent of all issues recorded in FY 1998. Additionally, five percent of all of the facilities evaluated were discovered to have issues with criteria. However, this percentage includes facilities where this criteria did not apply. In those facilities where the criteria did apply, seven percent had systemic issues with this criteria. In other words, whereas five percent of all facilities had systemic issues with performing special processes in accordance with process specifications, seven percent of the facilities that were actually performing special processes had systemic issues with following the process specifications.

3.6.1.1 Systemic Findings and Observations

The 21 evaluation criteria most frequently rated as systemic are presented in *Table 3-4*. These criteria accounted for more than one-half of all findings and systemic observations. As a group, they occurred at 77 percent of the facilities with systemic issues.

TABLE 3-4.—Predominant systemic findings and observations

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Total Systemic Findings and Observations	Percent of Domestic Facilities	Percent of Applicable Facilities with Issues
1	10Q1	Initial & periodic evaluations of suppliers	34	5%	6%	8%
2	4P9	Completed product/part identification	33	5%	6%	6%
3	15M1	Internal auditing program	29	5%	5%	8%
4	12Q5	Identification of age control products	27	4%	5%	7%
5	10Q5	Flow down of technical & quality requirements	20	3%	4%	5%
6	4P4	Work instructions control manufacturing processes	18	3%	3%	4%
7	11Q1	Control of nonconforming products	18	3%	3%	4%
8	5Q3	Accord with process specifications	17	3%	3%	6%
9	11Q2	Permanent identification of scrap material	17	3%	3%	4%
10	7Q1	Approval/inspection of tools & gauges	17	3%	3%	3%
11	4Q5	Inspection records	17	3%	3%	3%
12	4Q1	Inspection methods and plans	16	3%	3%	3%
13	4Q12	Completion of all inspections & tests	15	2%	3%	3%
14	10Q8	Verification of raw material	14	2%	3%	3%
15	10Q10	Receiving inspection	14	2%	3%	3%
16	2E2	Drawing control system	12	2%	2%	2%
17	7Q3	Tool & gauge recall system	11	2%	2%	2%
18	2E7	Design/Technical data document control	11	2%	2%	2%
19	10Q2	Use of approved suppliers	11	2%	2%	2%
20	2C1	Minor design change approval	10	2%	2%	3%
21	4P3	Work instructions reflect tech data	10	2%	2%	2%

Table 3-5 illustrates that many of the most significant systemic issues have been significant for the last four years. The table lists all of the criteria that have been within the top tenth percentile for each of the years from FY 1995 to FY 1998. The criteria are ranked by their significance over the four-year period. The columns “FY 1998,” “FY 1997,” “FY 1996,” and “FY 1995” indicate whether the criteria was a top issue for that year. Of the 21 criteria listed, 16 were top issues in at least two of the four years listed.

TABLE 3-5.—Four-year trend of most predominant systemic issues – by criteria

4-Year Rank	Criteria	FY 1998	FY 1997	FY 1996	FY 1995
1	10Q1 Initial & periodic evaluations of suppliers	X	X	X	X
2	4P9 Completed product/part identification	X	X	X	X
3	15M1 Internal auditing program	X	X	X	X
4	11Q1 Control of nonconforming products	X	X	X	X
5	5Q3 Accord with process specifications	X	X	X	
6	10Q10 Receiving inspection		X	X	X
7	4P4 Work instructions control manufacturing processes	X	X		X
8	12Q5 Inspection methods and plans	X		X	
9	10Q5 Flow down of technical & quality requirements	X	X		X
10	10Q2 Use of approved suppliers			X	X
11	10Q8 Verification of raw material			X	
12	4Q5 Inspection records	X	X		X
12	7Q1 Approval/inspection of tools & gauges	X			X
13	12Q3 Storage of conforming parts		X	X	
13	4M1 Operation within production limitations		X		
14	11Q2 Permanent identification of scrap material	X	X		
15	4Q1 Inspection methods and plans	X	X		X
16	2E2 Drawing control system				X
17	2E1 Design change approval			X	X
18	10Q12 Records of receiving inspection			X	
19	4Q3 Issuance of inspection stamps			X	
<p>X Criteria within the top tenth percentile for the fiscal year</p> <p>"blank" Criteria within the lower 90th percentile for the fiscal year</p>					

3.6.1.2 Isolated Observations

The evaluation criteria that were most likely to have isolated observations are presented in *Table 3-6*. These 17 criteria accumulated more than one-half of all isolated observations. As a group, they occurred in some combination at 69 percent of the facilities with isolated issues.

TABLE 3-6.—*Predominant isolated observations*

Rank	Criteria	Description	Number of Isolated Observations	Percent of Total Isolated Observations	Percent of Domestic Facilities	Percent of Applicable Facilities with Issues
1	7Q1	Approval/inspection of tools & gauges	9	5%	2%	2%
2	2E2	Drawing control system	8	5%	1%	2%
3	12Q5	Identification of age control products	7	4%	1%	2%
4	11Q2	Permanent identification of scrap material	7	4%	1%	1%
5	2E7	Design/Technical data document control	6	3%	1%	1%
6	7Q14	Identification of gauges	6	3%	1%	1%
7	5Q2	Required qualifications/approvals	5	3%	1%	2%
8	5Q3	Accord with process specifications	5	3%	1%	2%
9	11Q1	Control of nonconforming products	5	3%	1%	1%
10	4Q1	Inspection methods and plans	5	3%	1%	1%
11	9Q3	NDI procedures/specifications available & used	4	2%	1%	3%
12	15M1	Internal auditing program	4	2%	1%	1%
13	4P4	Work instructions control manufacturing processes	4	2%	1%	1%
14	10Q2	Use of approved suppliers	4	2%	1%	1%
15	10Q10	Receiving inspection	4	2%	1%	1%
16	4P9	Completed product/part identification	4	2%	1%	1%
17	4Q12	Completion of all inspections & tests	4	2%	1%	1%

As *Table 3-7* illustrates, many of the most significant isolated observations have been significant for the last four years. The table lists all of the criteria that have been within the top tenth percentile for each of the years from FY 1995 to FY 1998. The criteria are ranked by their significance over the four-year period. The columns “FY 1998,” “FY 1997,” “FY 1996,” and “FY 1995” indicate whether the criteria was a top issue for that year. The top ten issues listed have been predominant issues for the last four years. It should be noted that all but 5 of the top 18 isolated observations listed below are also listed as top systemic issues in *Table 3-5*, reinforcing the conclusion made in *Section 3.3* that isolated observations are somehow correlated with systemic issues.

TABLE 3-7.—Four-year trend of most predominant isolated observations – by criteria

4-Year Rank	Criteria	FY 1998	FY 1997	FY 1996	FY 1995
1	12Q5 Identification of age control products	X	X	X	X
2	15M1 Internal auditing program		X	X	X
3	7Q1 Approval/inspection of tools & gauges	X	X		X
4	11Q1 Control of nonconforming products		X	X	
5	2E7 Design/Technical data document control	X		X	X
6	4P4 Work instructions control manufacturing processes		X	X	X
7	10Q1 Initial & periodic evaluations of suppliers		X	X	X
8	5Q3 Accord with process specifications	X		X	
9	2E2 Drawing control system	X			X
10	11Q2 Permanent identification of scrap material	X	X		X
11	10Q2 Use of approved suppliers			X	
12	2E1 Design change approval		X		
13	4Q12 Completion of all inspections & tests			X	
14	7Q4 Identification of gauges	X			
15	5Q2 Required qualifications/approvals	X			
16	4Q3 Issuance of inspection stamps			X	
17	4Q5 Inspection records			X	X
18	4P3 Work instructions reflect tech data				X
<p>X Criteria within the top tenth percentile for the fiscal year</p> <p>"blank" Criteria within the lower 90th percentile for the fiscal year</p>					

3.6.1.3 FAR-based Observations

The eight evaluation criteria with the greatest number of FAR-based observations are presented in *Table 3-8*. They account for just over half of all FAR-based observations. As a group, these few criteria occurred in 55 percent of the facilities with FAR-based observations. The FAA should consider these criteria during the review of an approval holder's data (e.g., quality system procedures) prior to acceptance.

TABLE 3-8.—*Predominant FAR-based observations*

Rank	Criteria	Description	Number of FAR-based Observations	Percent of Total FAR-based Observations	Percent of Domestic Facilities	Percent of Applicable Facilities with Issues
1	4P9	Completed product/part identification	6	12%	1%	1%
2	4Q2	Location of inspection stations	5	10%	1%	1%
3	1Q6	Record retention schedule	3	6%	1%	1%
4	1Q4	Quality Manual	3	6%	1%	1%
5	5Q3	Accord with process specifications	2	4%	0.4%	1%
6	8E1	Test procedures/instructions established	2	4%	0.4%	1%
7	2E8	Major/minor design changes	2	4%	0.4%	0.5%
8	4P4	Work instructions control manufacturing processes	2	4%	0.4%	0.4%

A year-to-year comparison of FAR-based observations at the criteria level would be inappropriate. Due to the relatively infrequent occurrence of FAR-based observations, and the sheer number of possible criteria to categorize them, 227 criteria in total, the number of observations in any given criteria for a year is very small. Considerable variation in the data would result merely from the small sample size being analyzed, and would not be indicative of any trends.

3.6.2 A Facility Focus

This section lists the criteria issues separated by facility type. Only that data specific to the particular facility type referenced in the table caption is used in the frequency calculations. This allows the reader to use these tables to focus on the issues pertinent to a particular facility type without bias from the other facility types. For example, the data from the relatively few PC holders is not skewed by the data from the much larger population of PMA holders.

As in the previous subsection, the table column titled “Percent of Domestic Facilities” represents the proportion of facilities evaluated that had findings and/or observations recorded. The column titled “Percent of Applicable Facilities with Issues” provides the frequency of findings and/or observations reported at those facilities where the criteria was implemented, and is therefore weighted for applicability of the specific criteria, i.e., it represents only those facilities where the criteria has been implemented. This column compares those criteria that are not widely utilized throughout the industry on a level playing field with those criteria that are universally implemented.

3.6.2.1 Systemic Findings and Observations

Tables 3-9 to 3-12 separate systemic findings and systemic observations by facility type. For clarity, only the top issues are reported in these subsections; however, a full listing of the data can be found in *Appendix C*. Even though only 19 percent of the criteria are reported in these four tables, a total of 64 percent of all systemic issues are represented.

TABLE 3-9.—*Predominant systemic findings and observations — PC holders*

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Total Systemic Issues for PC Holders	Percent of PC Facilities	Percent of Applicable Facilities with Issues
1	10Q10	Receiving inspection	5	4%	11%	14%
2	4Q12	Completion of all inspections & tests	5	4%	11%	12%
3	10Q5	Flow down of technical & quality requirements	4	3%	9%	12%
4	5Q3	Accord with process specifications	4	3%	9%	11%
5	11Q1	Control of nonconforming products	4	3%	9%	10%
6	4P3	Work instructions reflect tech data	4	3%	9%	10%
7	12Q5	Identification of age control products	4	3%	9%	10%
8	14C3	Submittal of quality system data changes	3	2%	7%	8%
8	15M1	Internal auditing program	3	2%	7%	8%
9	4P4	Work instructions control manufacturing processes	3	2%	7%	8%
10	1Q4	Quality Manual	3	2%	7%	7%
10	2E2	Drawing control system	3	2%	7%	7%
11	4Q5	Inspection records	3	2%	7%	7%
12	9Q9	Records of compliance	2	2%	5%	6%
13	5Q1	Equipment available & calibrated	2	2%	5%	6%
13	5Q4	Records maintained	2	2%	5%	6%
14	4E2	New/changed process test substantiation	2	2%	5%	5%
14	8E2	Control of test procedure/instruction changes	2	2%	5%	5%
14	11Q2	Permanent identification of scrap material	2	2%	5%	5%
14	12Q2	Special environmental controls	2	2%	5%	5%
15	7Q3	Tool & gauge recall system	2	2%	5%	5%
15	8E1	Test procedures/instructions established	2	2%	5%	5%
15	12Q3	Storage of conforming parts	2	2%	5%	5%
16	2E1	Design change approval	2	2%	5%	5%
16	12Q1	Prevention of part damage/contamination	2	2%	5%	5%

TABLE 3-10.—*Predominant systemic findings and observations — PMA holders*

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Total Systemic Issues for PMA Holders	Percent of PMA Facilities	Percent of Applicable Facilities with Issues
1	10Q1	Initial & periodic evaluations of suppliers	21	7%	7%	9%
2	4P9	Completed product/part identification	21	7%	7%	8%
3	15M1	Internal auditing program	12	4%	4%	6%
4	4Q1	Inspection methods and plans	11	4%	4%	4%
5	10Q5	Flow down of technical & quality requirements	10	3%	3%	4%
6	10Q8	Verification of raw material	10	3%	3%	4%
7	2C1	Minor design change approval	9	3%	3%	4%
8	7Q1	Approval/inspection of tools & gauges	9	3%	3%	3%
9	12Q5	Identification of age control products	8	3%	3%	4%
10	11Q2	Permanent identification of scrap material	8	3%	3%	3%
11	2E7	Design/Technical data document control	7	2%	2%	3%
12	11Q1	Control of nonconforming products	7	2%	2%	3%
13	2E2	Drawing control system	7	2%	2%	3%
13	4M1	Operation within production limitations	7	2%	2%	3%
14	4Q5	Inspection records	7	2%	2%	3%
15	5Q3	Accord with process specifications	6	2%	2%	4%
16	7Q3	Tool & gauge recall system	6	2%	2%	2%
17	7Q16	Inaccurate tools & gauges identified	5	2%	2%	2%
18	4Q3	Issuance of inspection stamps	5	2%	2%	2%
19	10Q2	Use of approved suppliers	5	2%	2%	2%
20	4Q12	Completion of all inspections & tests	5	2%	2%	2%
21	10Q10	Receiving inspection	5	2%	2%	2%

TABLE 3-11.—*Predominant systemic findings and observations — priority parts suppliers*

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Total Systemic Issues for Suppliers	Percent of Supplier Facilities	Percent of Applicable Facilities with Issues
1	11Q2	Permanent identification of scrap material	4	7%	5%	6%
2	7Q1	Approval/inspection of tools & gauges	4	7%	5%	5%
3	10Q1	Initial & periodic evaluations of suppliers	3	5%	4%	6%
4	10Q5	Flow down of technical & quality requirements	3	5%	4%	5%
5	12Q5	Identification of age control products	3	5%	4%	5%
6	15M1	Internal auditing program	3	5%	4%	5%
7	4P4	Work instructions control manufacturing processes	3	5%	4%	4%
8	9Q14	Critical penetrant parameters identified	2	4%	3%	7%
9	9Q4	Tanks & solutions checked	2	4%	3%	6%
10	2E7	Design/Technical data document control	2	4%	3%	4%
11	11Q4	Material review record generated	2	4%	3%	3%
12	2E2	Drawing control system	2	4%	3%	3%
13	11Q1	Control of nonconforming products	2	4%	3%	3%
14	4Q5	Inspection records	2	4%	3%	3%

TABLE 3-12.—*Predominant systemic findings and observations — TSO authorization holders*

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Total Systemic Issues for TSO Holders	Percent of TSO Facilities	Percent of Applicable Facilities with Issues
1	12Q5	Identification of age control products	12	7%	9%	12%
2	15M1	Internal auditing program	11	7%	8%	13%
3	10Q1	Initial & periodic evaluations of suppliers	10	6%	8%	9%
4	4P4	Work instructions control manufacturing processes	8	5%	6%	7%
5	4P9	Completed product/part identification	8	5%	6%	6%
6	5Q3	Accord with process specifications	6	4%	5%	10%
7	2C4	Data submittal for TSO minor changes	6	4%	5%	5%
8	10Q2	Use of approved suppliers	5	3%	4%	4%
8	11Q1	Control of nonconforming products	5	3%	4%	4%
9	4Q5	Inspection records	5	3%	4%	4%
10	8E1	Test procedures/instructions established	4	2%	3%	4%
11	10Q8	Verification of raw material	4	2%	3%	4%
12	10Q10	Receiving inspection	4	2%	3%	3%
13	7Q2	Instructions for acceptance tooling	3	2%	2%	3%
14	11Q2	Permanent identification of scrap material	3	2%	2%	3%
15	10Q5	Flow down of technical & quality requirements	3	2%	2%	3%
16	4P2	Work instructions prepared	3	2%	2%	3%
17	2E1	Design change approval	3	2%	2%	2%
18	4Q12	Completion of all inspections & tests	3	2%	2%	2%
19	1Q4	Quality Manual	3	2%	2%	2%

3.6.2.2 Isolated Observations

Tables 3-13 to 3-16 separate isolated observations by facility type. For clarity, only the top issues are reported in these tables; however, a full listing of the data can be found in *Appendix C*. Even though only 13 percent of the criteria are reported in these four tables, more than one-half of all isolated observations are represented.

TABLE 3-13.—*Predominant isolated observations — PC holders*

Rank	Criteria	Description	Number of Isolated Observations	Percent Isolated Observations for All PC Holders	Percent of PC Facilities	Percent of Applicable Facilities with Issues
1	11Q2	Permanent identification of scrap material	4	9%	9%	11%
2	7Q14	Identification of gauges	4	9%	9%	10%
3	4P4	Work instructions control manufacturing processes	3	7%	7%	8%
4	2E2	Drawing control system	3	7%	7%	7%
5	15M1	Internal auditing program	2	4%	5%	5%
6	11Q1	Control of nonconforming products	2	4%	5%	5%
7	12Q5	Identification of age control products	2	4%	5%	5%
8	2E7	Design/Technical data document control	2	4%	5%	5%
9	3AE1	Software Configuration Management Plan	1	2%	2%	14%

TABLE 3-14.—*Predominant isolated observations — PMA holders*

Rank	Criteria	Description	Number of Isolated Observations	Percent Isolated Observations for All PMA Holders	Percent of PMA Facilities	Percent of Applicable Facilities with Issues
1	5Q3	Accord with process specifications	3	8%	1%	2%
2	12Q5	Identification of age control products	3	8%	1%	1%
3	4Q1	Inspection methods and plans	3	8%	1%	1%
4	4P9	Completed product/part identification	3	8%	1%	1%
5	17Q5	Record of completed work	2	5%	1%	8%
6	5Q2	Required qualifications/approvals	2	5%	1%	1%
7	5E1	All special processes in use identified	2	5%	1%	1%
8	10Q8	Verification of raw material	2	5%	1%	1%
9	2E2	Drawing control system	2	5%	1%	1%
10	10Q10	Receiving inspection	2	5%	1%	1%

TABLE 3-15.—*Predominant isolated observations — priority parts suppliers*

Rank	Criteria	Description	Number of Isolated Observations	Percent Isolated Observations for All Suppliers	Percent of Priority Parts Supplier Facilities	Percent of Applicable Facilities with Issues
1	9Q3	NDI procedures/specifications available & used	3	13%	4%	8%
2	7Q1	Approval/inspection of tools & gauges	3	13%	4%	4%
3	10Q2	Use of approved suppliers	2	8%	3%	3%
4	9Q14	Critical penetrant parameters identified	1	4%	1%	4%

TABLE 3-16.—*Predominant isolated observations — TSO authorization holders*

Rank	Criteria	Description	Number of Isolated Observations	Percent Isolated Observations for All TSO Holders	Percent of TSO Holders	Percent of Applicable Facilities with Issues
1	7Q1	Approval/inspection of tools & gauges	4	6%	3%	3%
2	2C4	Data submittal for TSO minor changes	3	4%	2%	3%
3	2E7	Design/Technical data document control	3	4%	2%	3%
4	5Q2	Required qualifications/approvals	2	3%	2%	4%
5	14C3	Submittal of quality system data changes	2	3%	2%	3%
6	15M1	Internal auditing program	2	3%	2%	2%
7	11Q2	Permanent identification of scrap material	2	3%	2%	2%
8	10Q1	Initial & periodic evaluations of suppliers	2	3%	2%	2%
9	8E1	Test procedures/instructions established	2	3%	2%	2%
10	4Q1	Inspection methods and plans	2	3%	2%	2%
11	12Q3	Storage of conforming parts	2	3%	2%	2%
12	2E1	Design change approval	2	3%	2%	2%
12	10Q10	Receiving inspection	2	3%	2%	2%
13	2E2	Drawing control system	2	3%	2%	2%
14	1Q5	Tags, forms, etc., described	2	3%	2%	2%
15	4Q12	Completion of all inspections & tests	2	3%	2%	2%

3.6.3 Summary of Criteria Issues

A comparative analysis was performed on those criteria with systemic issues within the top fifth percentile both industry-wide and facility-type specific. This type of analysis highlights differences among the various facility types. *Figure 3-22* projects how the various facility types compare to the rest of the industry in the top 14 systemic issues. The reader can use this chart in order to compare the performance of a particular facility type to the rest of the aviation community. For example, figure 3-22 indicates that there is a significantly higher percentage of PC holders with systemic issues in flowdown of technical and quality requirements and in receiving inspection than the rest of the industry. The figure also indicates that priority part suppliers have a slightly lower percentage of facilities with systemic issues in completed product/part identification than the other facility types.

Criteria	PC	PMA	PPS	TSO
10Q1 Initial & periodic evaluation of suppliers				
15M1 Internal auditing program				↑
4P9 Completed product/part identification			↓	
10Q5 Flow down of technical & quality requirements	↑			
5Q3 Accord with process specifications				
11Q1 Control of nonconforming products	↑			
12Q5 Identification of age control products				
10Q10 Receiving Inspection	↑			
4Q1 Inspection methods and plans				↑
2C1/ 2C4 Minor design change approval		↓		↑
4M1 Operation within production limitations				
4Q12 Completion of all Inspections & tests				
10Q2 Use of approved suppliers				↑
1M5 Policy document review	↑			

↑ Significantly higher than industry average

↑ Slightly higher than industry average

↓ Slightly lower than industry average

↓ Significantly lower than industry average

"Blank" Consistent with industry average

Figure 3-22.—Comparison of the various facility types – percentage of facilities with systemic issues in the criteria.

3.7 Trend Analysis

ACSEP evaluation results have been collected in a standard and consistent manner sufficient to allow trend analysis since FY 1995. Since only four years of data are available, only preliminary analysis can be performed. At least one more year of data will be needed before any conclusive trend analysis can be reported. Notwithstanding, this report presents the preliminary trend analysis for consideration. The reader is, however, cautioned against placing too much reliance on any suggested trends from such a small sample.

The figures present several pieces of data. The data points are the percentage of facilities that had at least one observation or finding for each of the given fiscal years. Error bars are provided for each data point. Each figure also contains two sets of lines. The solid line is the linear regression of the data points. The dotted lines are the positive and negative statistical error for the regression line. A 90 percent confidence level was used in all cases to determine if a preliminary trend was indicated (an explanation as to the selection of the confidence level is discussed further in *Appendix E*).

Please note that the facility data presented in the following figures is not adjusted for the differences in system and process complexity among the various facility types. Therefore, the data for each facility type should be considered separately; and no comparison of the facility types can be made.

3.7.1 Systemic Issues

With the exception of priority parts suppliers, the proportion of facilities with systemic issues has remained relatively flat. There has been a 24 percent drop in priority parts suppliers with recorded systemic issues. The proportion of PC holders with systemic issues appears to be dropping slightly, however, not to a significant level as yet. The results of the preliminary trend analysis for systemic issues among the various facility types is presented in *figures 3-23 through 3-27*.

The data for PC holders appears to have an annual cyclical fluctuation. This fluctuation appears to be caused by a sampling bias introduced at the inception of ACSEP. Due to the relatively small number of PC holders, and the relative critical nature of these facilities, it is theorized that the initial selection of facilities to evaluate was not random. Additionally, since each PC holder is re-evaluated every two years, there is no variation in the biannual cycle of facility selection for evaluation. The other facility types would be far less affected by the initial selection bias. The greater number of facilities in the other facility types lessens the impact that a targeted selection of a few facilities would have on an otherwise random selection of facilities. It is theorized that the selection of PC holders to evaluate in a given year is not random. It appears that the selection of the other facility types, however, is random. Random selection of the facilities is essential in order to use the data to project results with statistical analysis. For this reason, all presentations of PC holder information is presented with two consecutive years pooled.

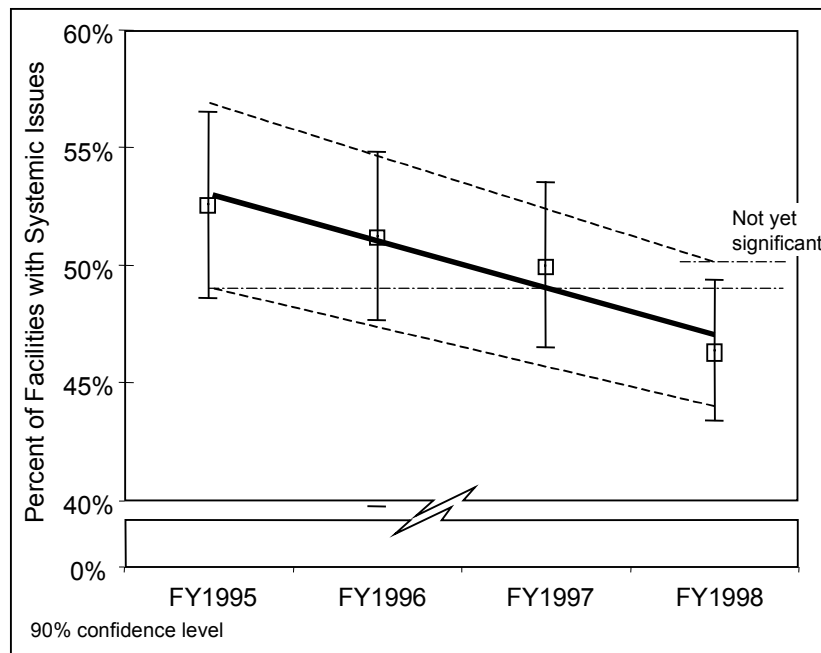


Figure 3-23.—Preliminary trend data for systemic issues — overall.

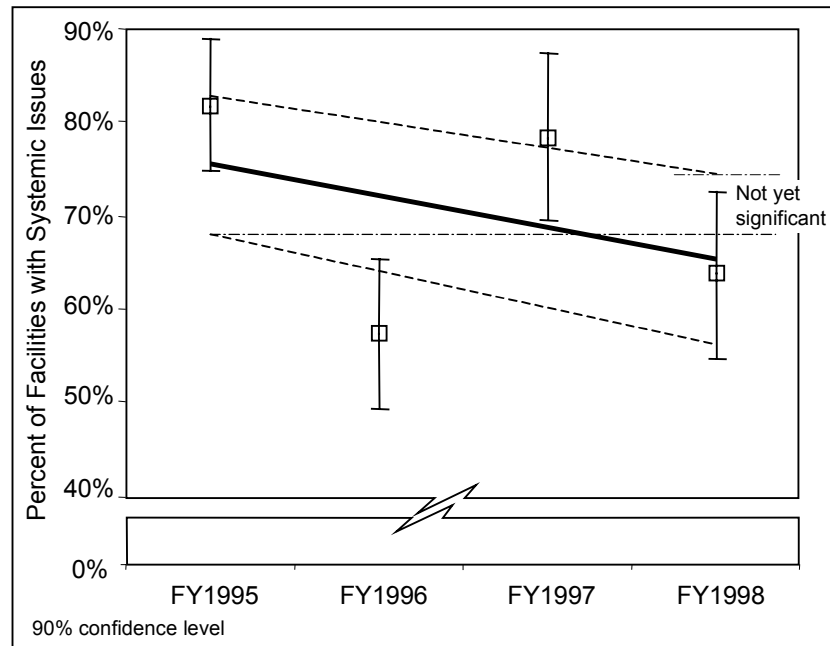


Figure 3-24.—Preliminary trend data for systemic issues — PC holders.

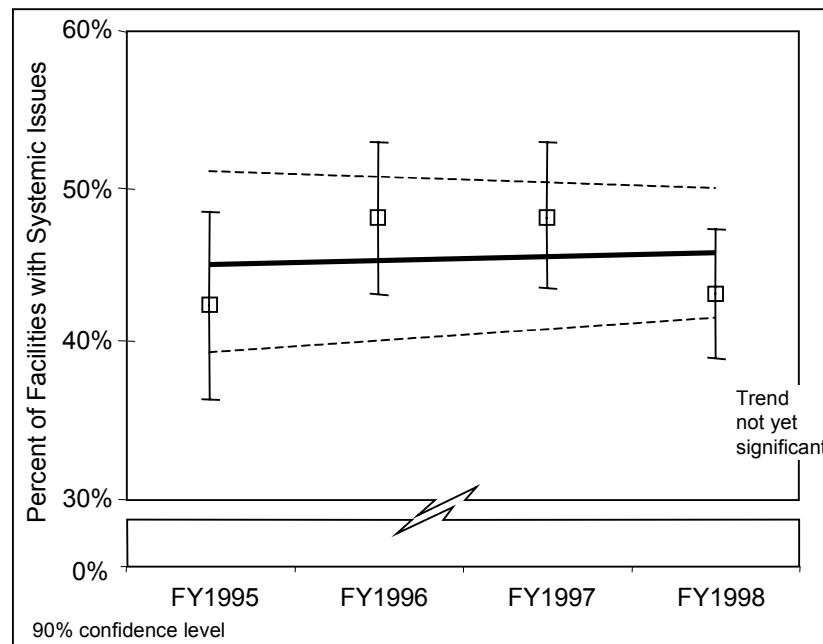


Figure 3-25.—Preliminary trend data for systemic issues — PMA holders.

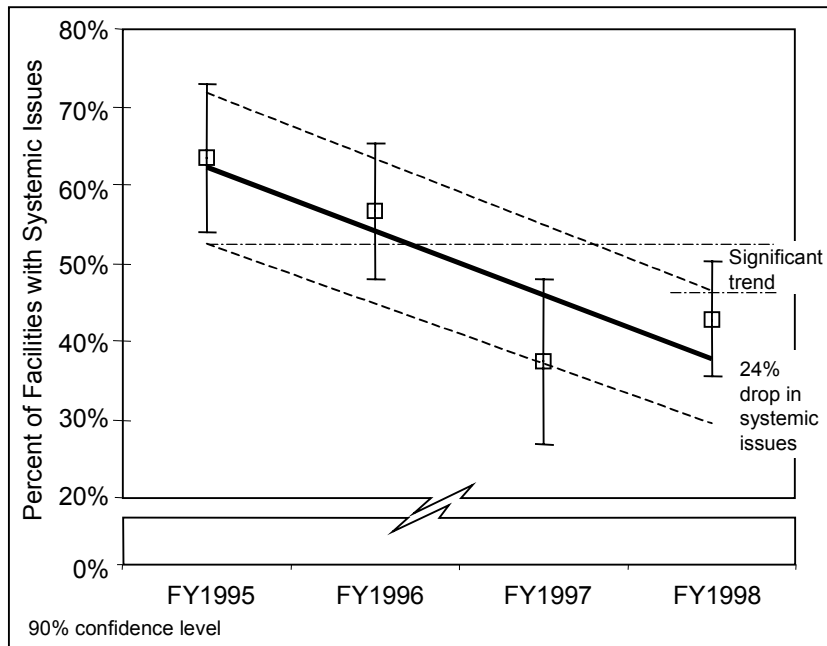


Figure 3-26.—Preliminary trend data for systemic issues — priority part suppliers.

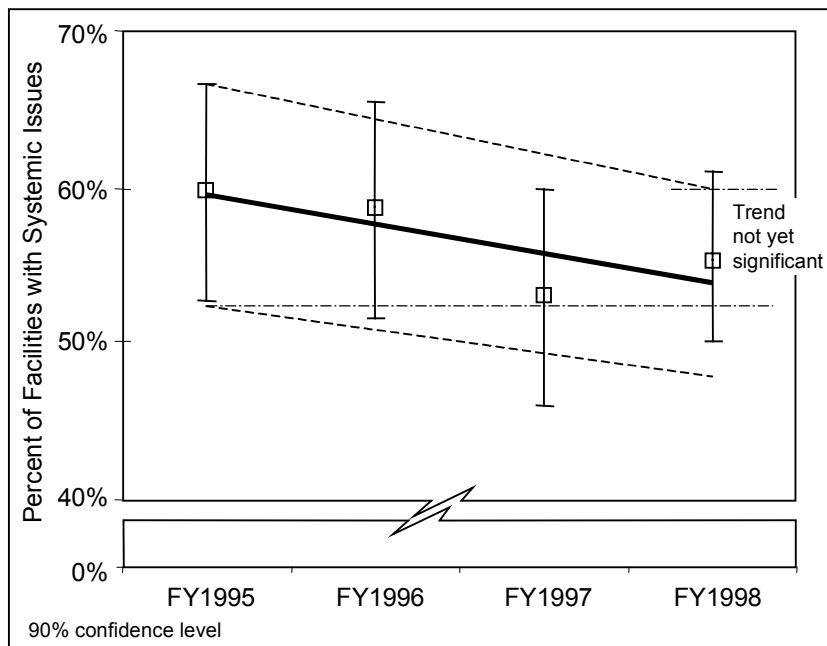


Figure 3-27.—Preliminary trend data for systemic issues — TSO authorizations.

3.7.1.1 Systemic Issue Trends at the Subsystem Level

The percentage of facilities with systemic issues appears to have dropped within some of the subsystems. The trend for all facilities with systemic issues illustrated in *Figure 3-23* will be represented in *Figure 3-28* using a more focused scale in order to offer a clear comparison of the trends illustrated in the following *figures 3-29 through 3-33*. It should be noted that, while there was not a statistically significant trend overall, five of the subsystems do exhibit a significant downward trend. The estimated reduction of facilities with systemic issues is listed in *Tables 3-17*.

TABLE 3-17.—Estimated reduction in facilities with systemic issues

Subsystem name	Percentage drop in facilities with systemic issues in the subsystem over the last four years	Estimated reduction in the number of facilities overall with systemic issues within the subsystem
Supplier Control	8%	147
Manufacturing Processes	8%	141
Design Data Control	7%	129
Testing	4%	58
Statistical Quality Control (SQC)	3%	22

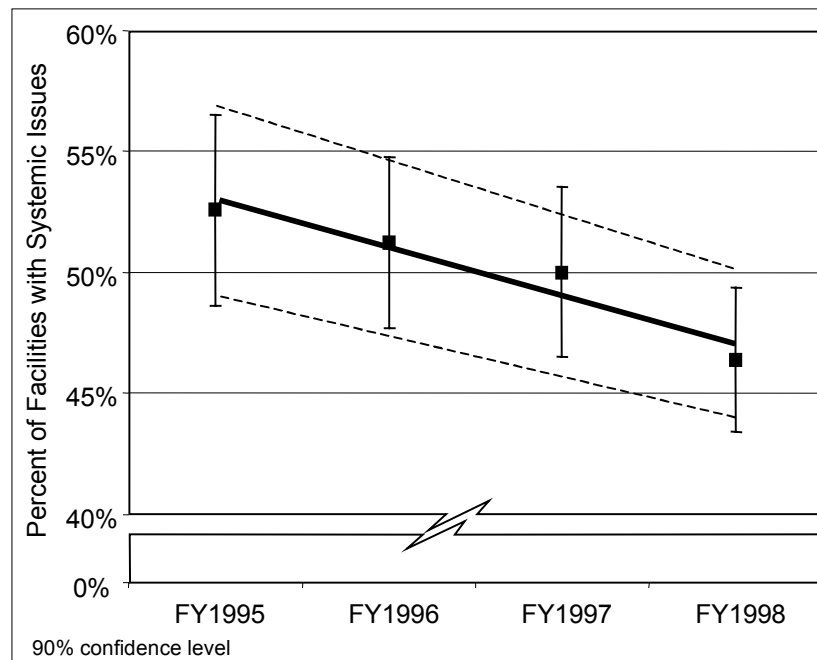


Figure 3-28.—Preliminary trend data for systemic issues — overall.

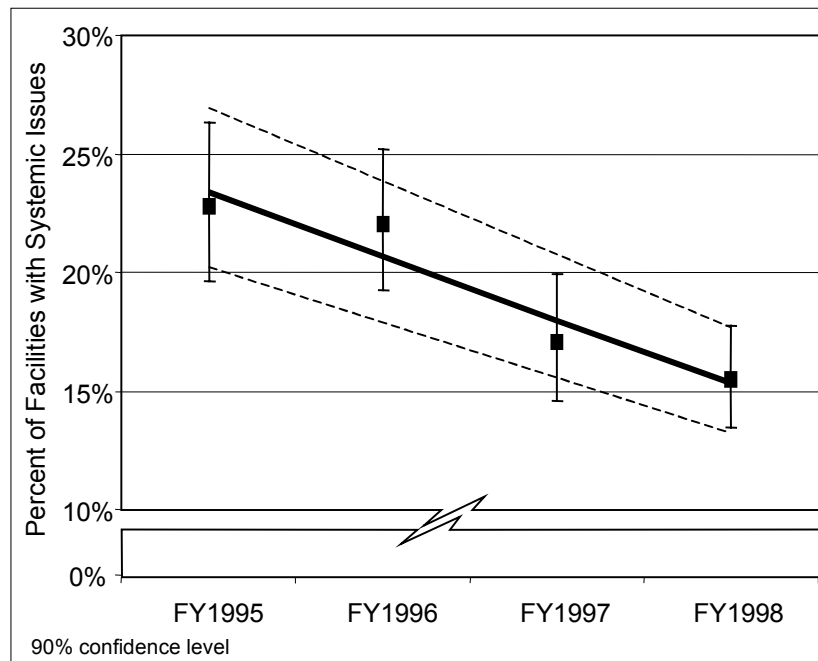


Figure 3-29.—Preliminary trend data for systemic issues —supplier control subsystem.

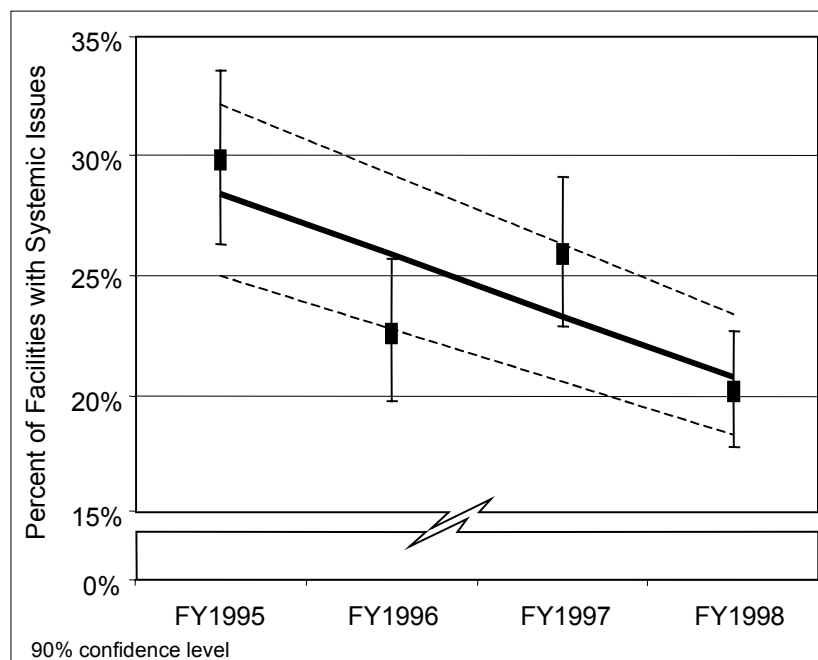


Figure 3-30.—Preliminary trend data for systemic issues — manufacturing processes subsystem.

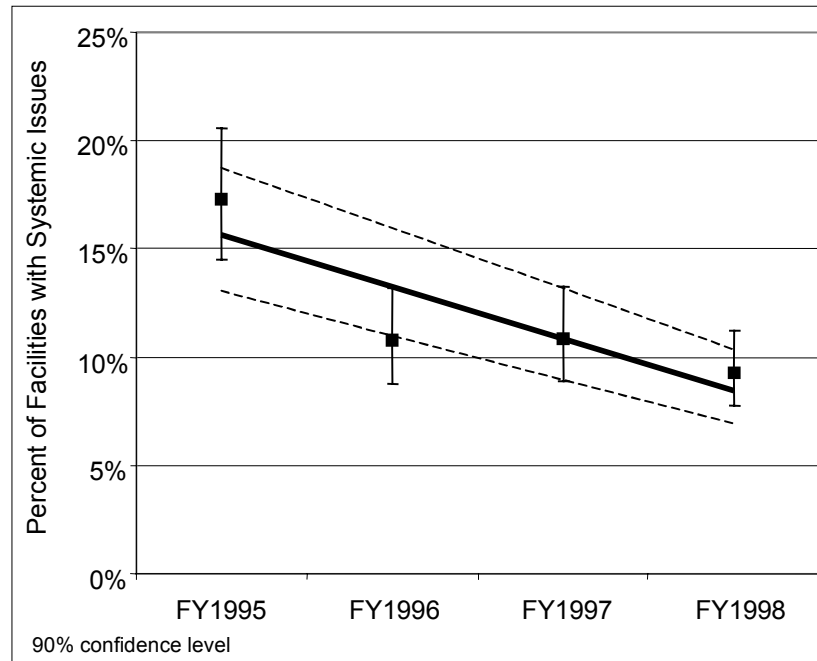


Figure 3-31.—Preliminary trend data for systemic issues — design data control subsystem.

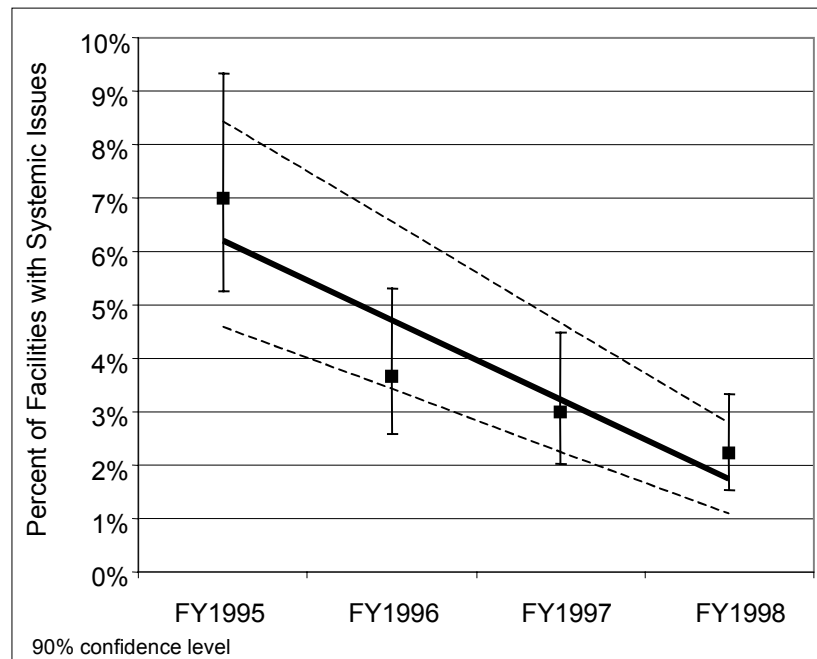


Figure 3-32.—Preliminary trend data for systemic issues — testing subsystem.

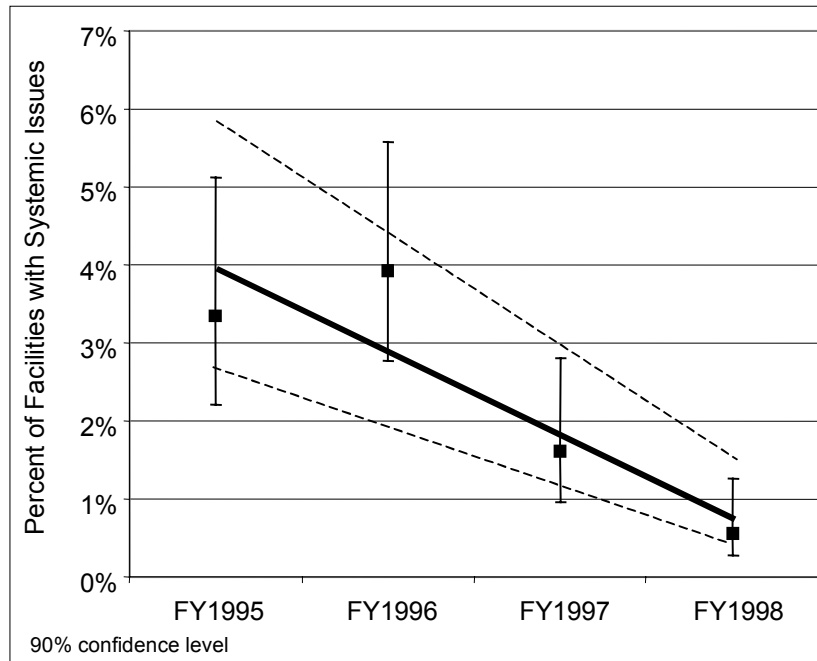


Figure 3-33.—Preliminary trend data for systemic issues — statistical quality control (SQC) subsystem.

3.7.1.2 Systemic Issue Trends at the Criteria Level

Preliminary trend analysis was performed on the systemic issues within criteria 10Q1: Initial & periodic evaluations of suppliers and criteria 11Q1: Control of nonconforming products. These two criteria were chosen because they have been prominent issues over the last four years and there appears to be a statistically significant trend. Any trend in these criteria would have a large impact on the compliance levels of all facility types. This preliminary analysis suggests a drop in their occurrence. However, the reader is cautioned that the results of this analysis is preliminary. Additional data is required before any defensible trends can be established.

TABLE 3-18.—Preliminary four-year trend of systemic issues—criteria level

Criteria	Criteria name	Percentage drop in facilities with systemic issues in the criteria over the last four years
10Q1	Initial & periodic evaluations of suppliers	7%
11Q1	Control of nonconforming products	4%

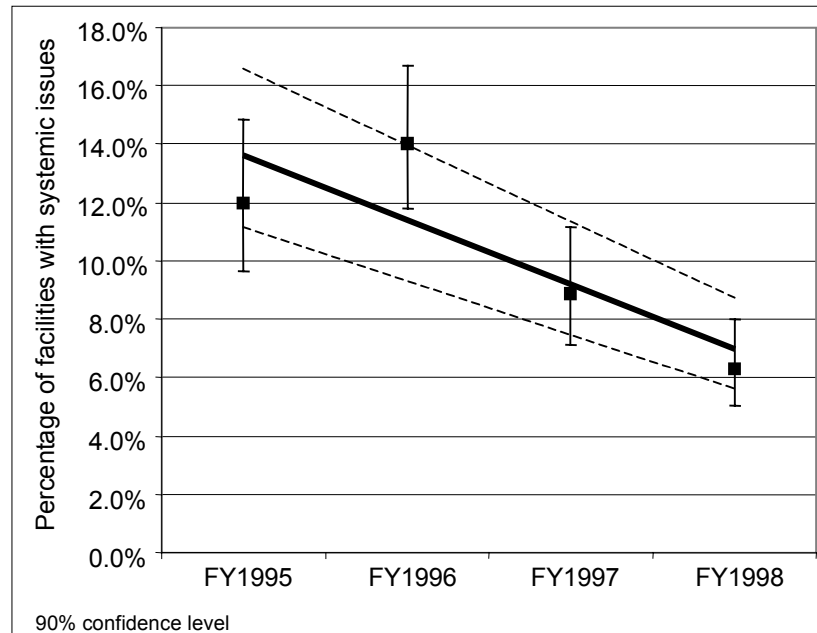


Figure 3-34.—Preliminary trend data for systemic issues —Criteria 10Q1: Initial & periodic evaluations of suppliers.

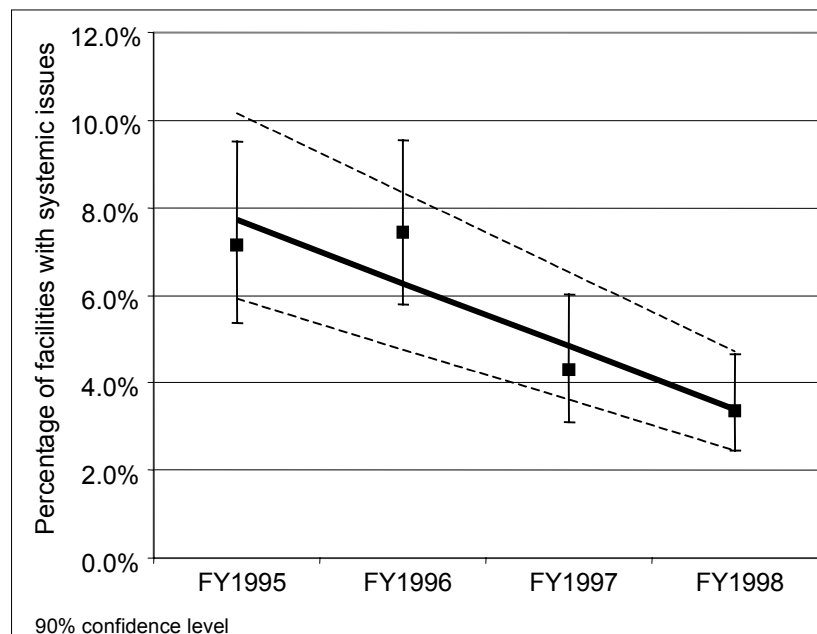


Figure 3-35.—Preliminary trend data for systemic issues —Criteria 11Q1: Control of nonconforming products.

3.7.2 Isolated Observations

Isolated observations appear to be trending downward overall. The data suggests that this downward trend applies to all the facility types. The results of the preliminary trend analysis of isolated observations are presented in *figures 3-36 through 3-40*.

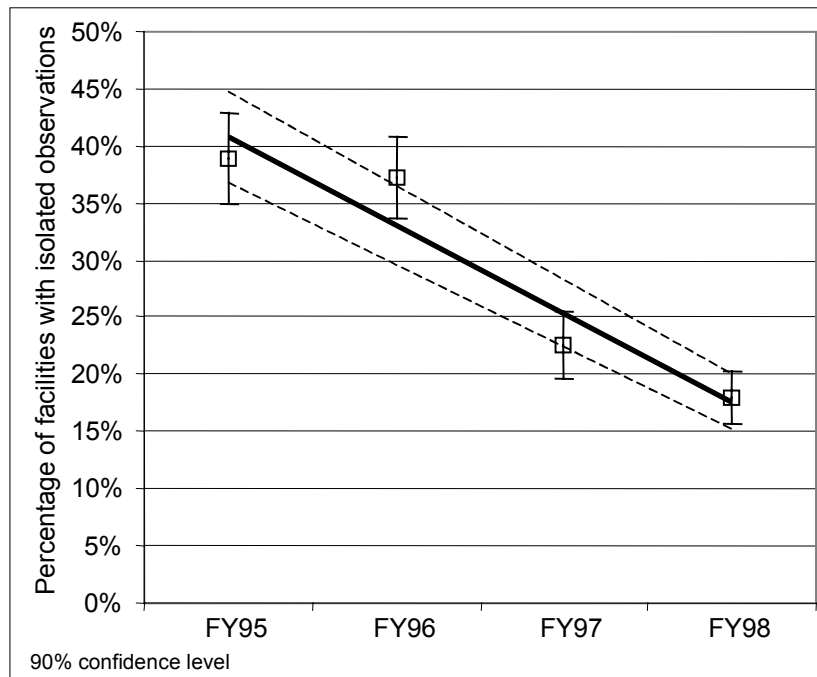


Figure 3-36.—Preliminary trend data for isolated observations —overall.

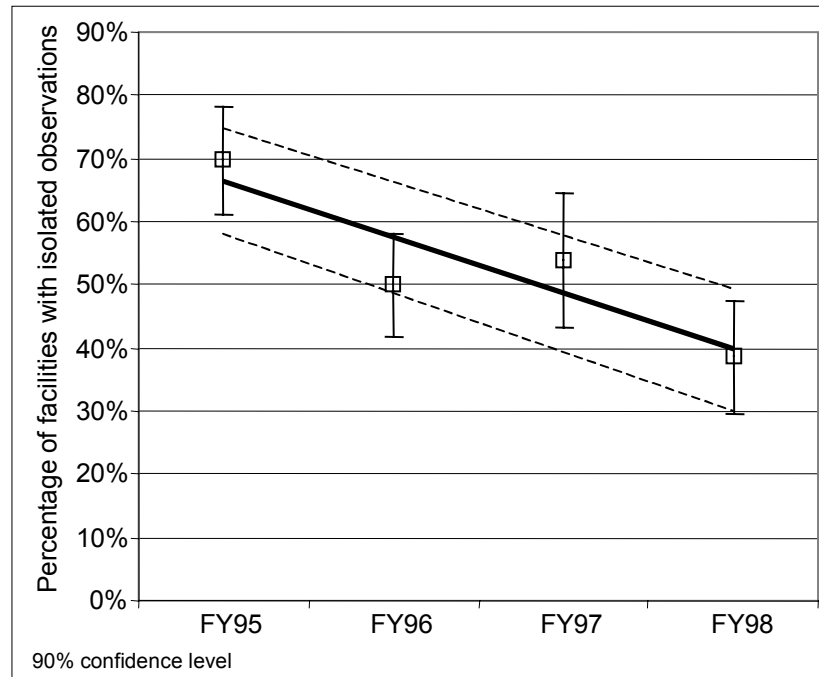


Figure 3-37.—Preliminary trend data for isolated observations —PC holders.

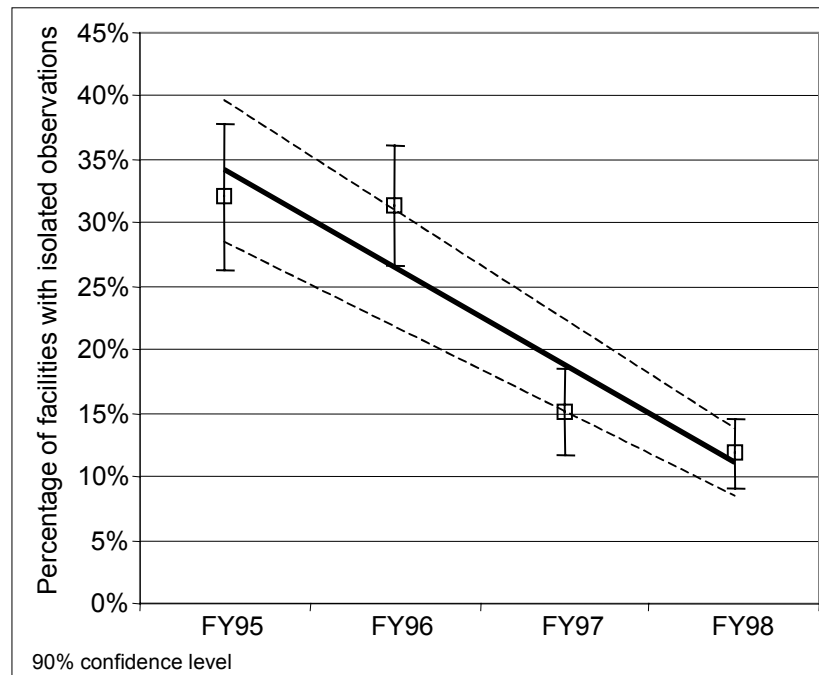


Figure 3-38.—Preliminary trend data for isolated observations —PMA holders.

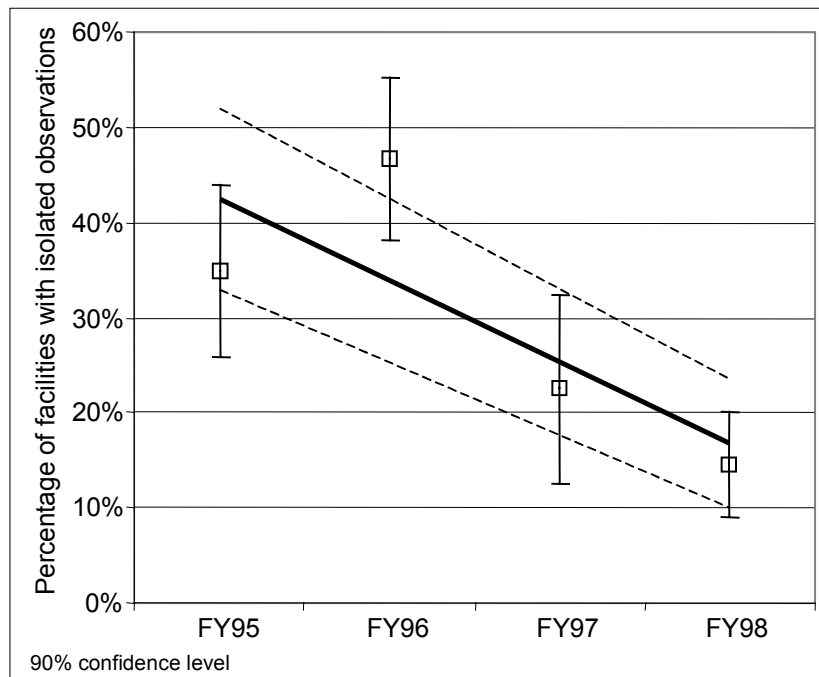


Figure 3-39.—Preliminary trend data for isolated observations —priority part suppliers.

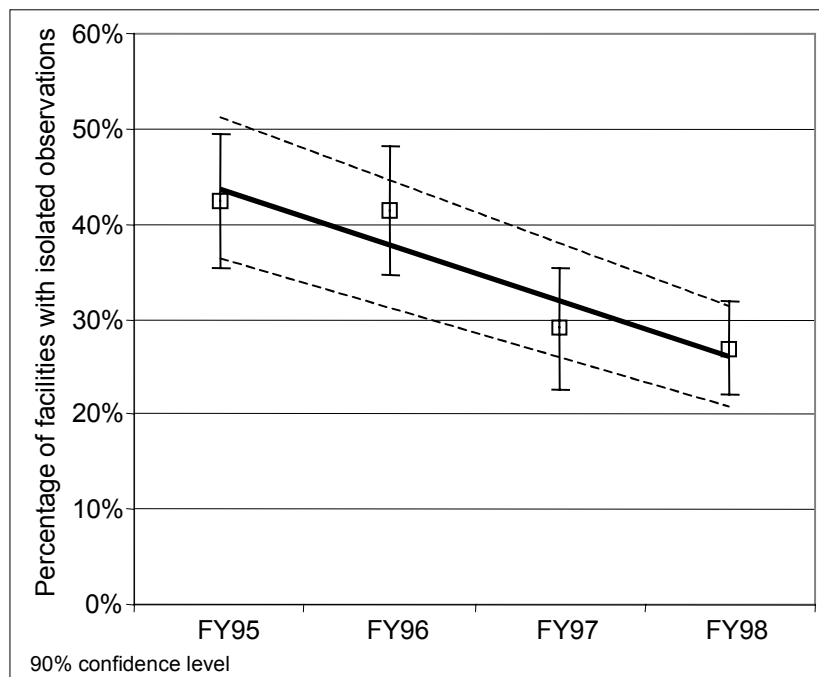


Figure 3-40.—Preliminary trend data for isolated observations —TSO authorization holders.

3.7.3 FAR-based Observations

FAR-based observations appear to be occurring less often both overall and specifically at PMA holders. The preliminary trend for PC holders also appears to be slightly downward. The trend for TSO authorization holders appears to be essentially flat for the last four years. The results of the preliminary trend analysis of FAR-based observations are presented in *figures 3-41 through 3-44*.

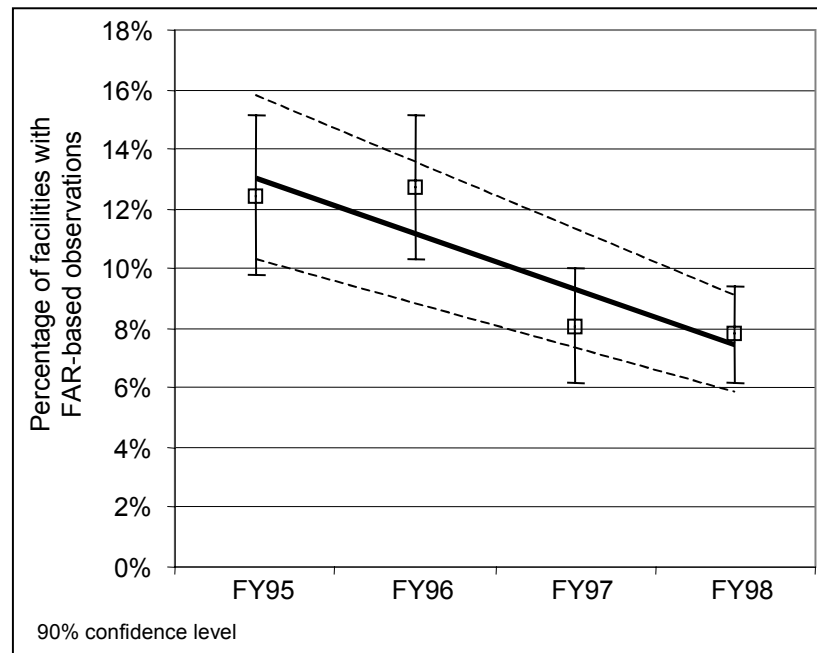


Figure 3-41.—Preliminary trend data for FAR-based observations —overall.

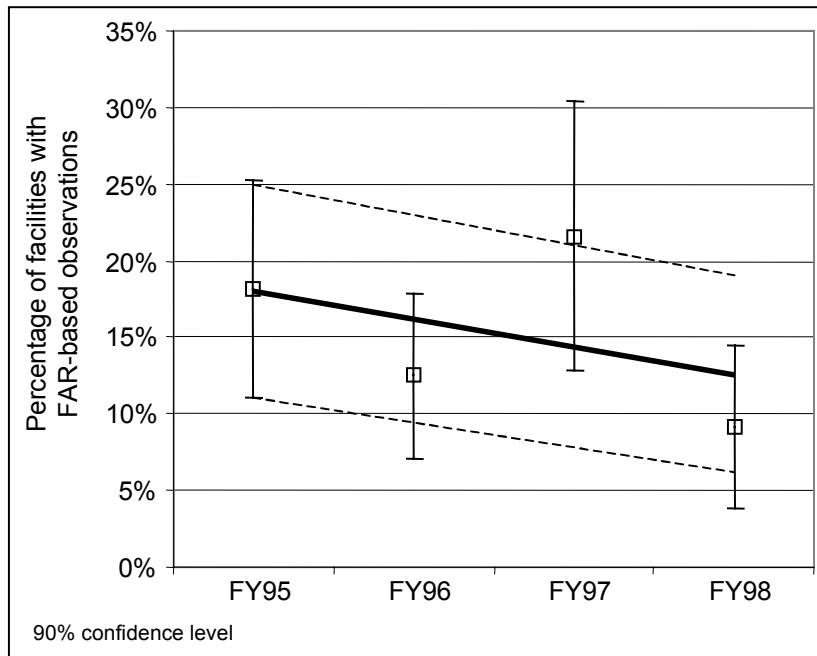


Figure 3-42.—Preliminary trend data for FAR-based observations —PC holders.

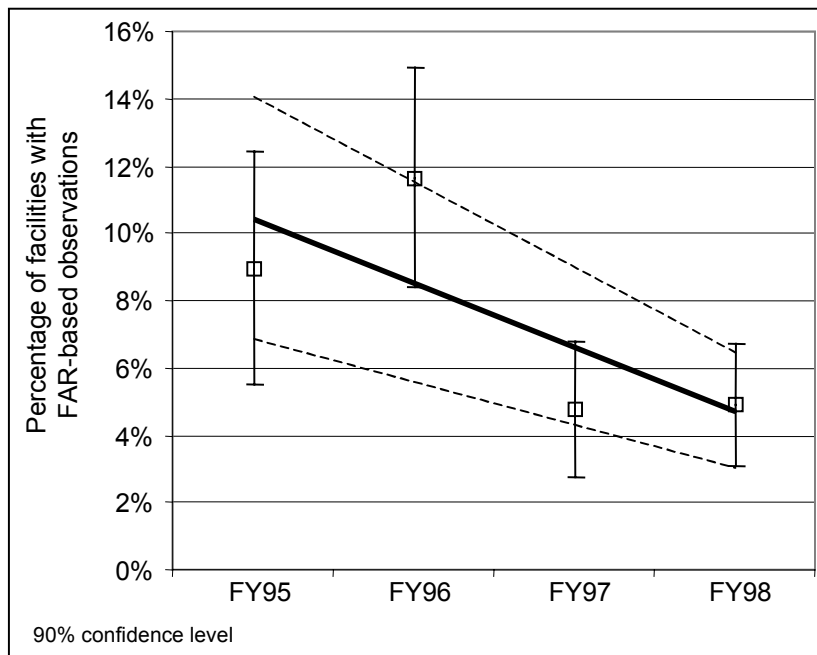


Figure 3-43.—Preliminary trend data for FAR-based observations —PMA holders.

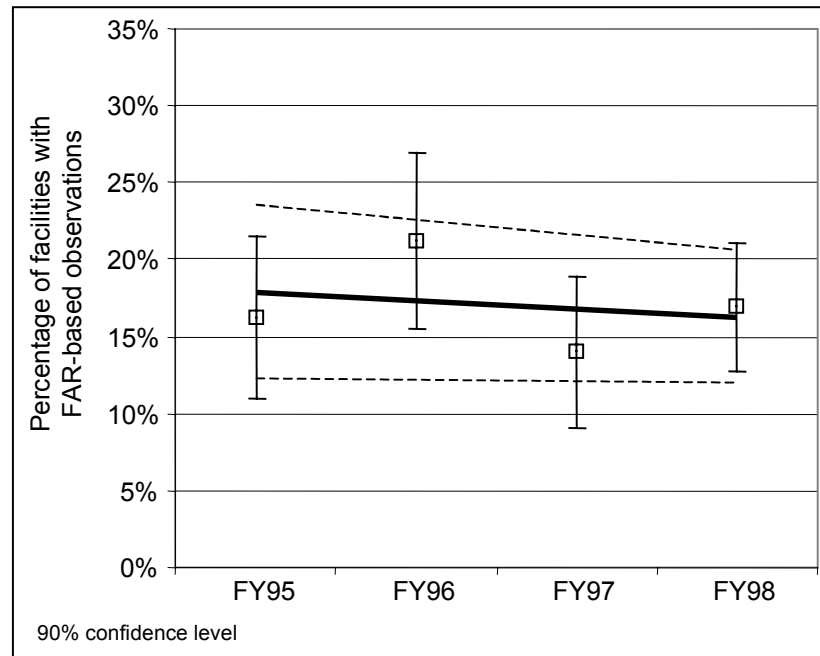


Figure 3-44.—Preliminary trend data for FAR-based observations —TSO authorization holders.

3.8 Internal Audit

3.8.1 What is the Impact of a Discrepant Internal Audit Program?

Building on an analysis introduced in the FY 1996 report, a correlation analysis was performed on the differences between the level of and incidence of systemic issues for those facilities with and without an effective internal audit program. The first part of the analysis compares the probability of systemic issues occurring at facilities with effective and ineffective internal audit programs. The second part of the analysis focused on the number of issues there were at the two groups of facilities.

The null hypothesis investigated for the first half of the analysis is that the probability of a facility having systemic issues in areas other than internal audit is independent from a facility having an effective internal audit program. The alternative hypothesis is that a facility with an ineffective internal audit program has a higher probability of systemic issues in areas other than internal audit.

The following definitions were used:

- | | | |
|------------------------------------|---|--|
| Effective audit program | – | The facility had implemented an internal audit program as described in Order 8100.7 and had not received findings nor systemic observations in the Internal Audit subsystem. It should be noted that no qualitative assessment of the internal audit program was made by the FAA. Any facility with an internal audit program, as defined in Order 8100.7, that was found to be in compliance with its own procedures and policies was deemed to have an effective internal audit program for the purposes of analysis only. |
| Ineffective internal audit program | – | Those facilities where an internal audit program was in place, but that program had findings or systemic observations against it. <i>Please note, the findings and observations against the internal audit program were subtracted in order to provide an unbiased analysis.</i> |
| No internal audit program | – | Facilities where internal audit was determined to be either not in place or not applicable. <i>Facilities where the Internal Audit subsystem had not been evaluated were not included in the analysis as their internal audit status could not be ascertained. Any facility that received a finding or systemic observation for their internal audit program because the documented internal audit program had not yet been implemented or had not been used for several years was also excluded from the analysis.</i> |

Several analysis methods were used in order to verify the results: chi-squared contingency tables, confidence intervals (as seen in the figures), and pooled Z-tests for significance. All tests supported the null hypothesis; i.e., a facility with systemic issues in its internal audit program is twice as likely to have systemic issues (in subsystems other than internal audit) than a facility having an internal audit program that does not have any systemic issues. As *figure 3-45* illustrates, the relationship between a facility not following its documented internal audit procedures and the probability of systemic issues is extremely strong (the analysis has a p-value¹³ of less than 1.7×10^{-10}). In fact, almost all of the facilities having systemic issues with their internal audit programs also had systemic issues in other areas.

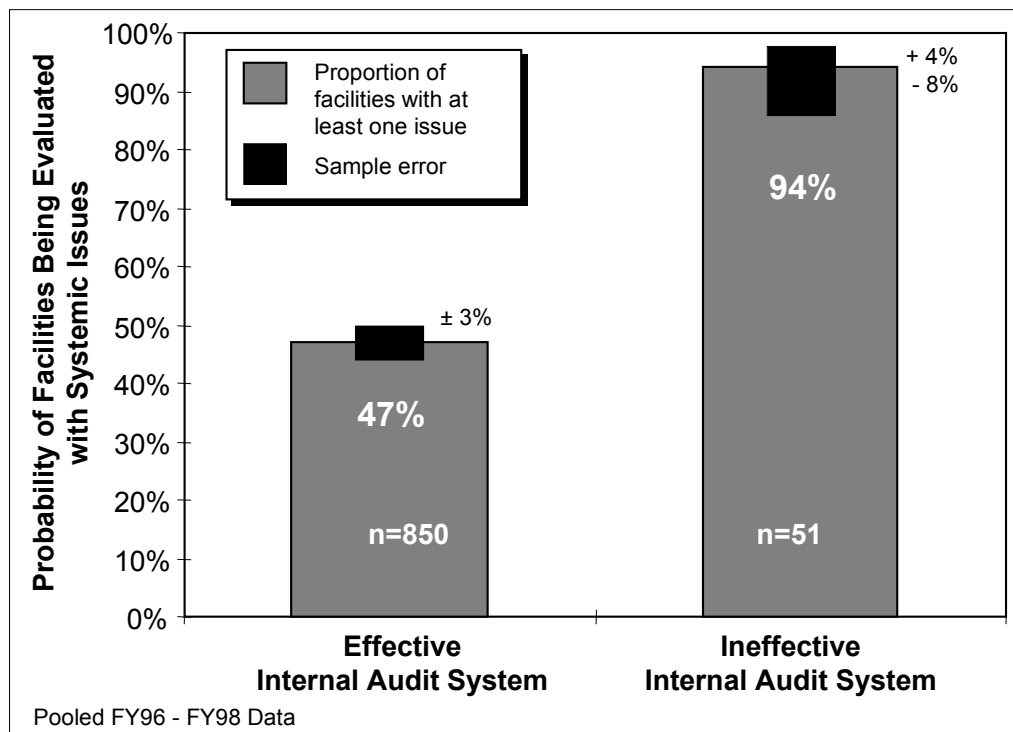


Figure 3-45.—Comparison of systemic issues for facilities with effective and ineffective internal audit programs.

The second part of the analysis focused on whether facilities with ineffective internal audit programs had more findings and systemic observations. The null hypothesis investigated whether the number of systemic issues in areas other than internal audit is independent from a facility having an effective internal audit program. The alternative

¹³ The p-value is one measure of the strength of a conclusion. For these analyses, a p-value less than 0.1 would be considered statistically significant. The smaller the p-value, the stronger the evidence to reject the null hypothesis. Most texts covering statistics will contain a detailed description of p-values and their application.

hypothesis was that facilities with ineffective internal audit programs have more systemic issues in areas other than internal audit.

The definitions for effective and ineffective internal audit given previously were used. As in the previous analysis, several statistical tests¹⁴ were performed in order to confirm the findings. The analysis clearly indicated an increase in the number of findings and systemic observations for facilities with ineffective internal audit over those with effective internal audit. A p-value of less than 2.0×10^{-16} was obtained from the analysis of all facilities, *see figure 3-46*, and a p-value of 1.2×10^{-4} was obtained from the analysis of only those facilities with at least one systemic issue other than within the internal audit subsystem, *see figure 3-47*. The comparison of the respective frequency distributions is shown in *figure 3-48*. With this relationship established, it is appropriate to view the average number of systemic issues for facilities with ineffective internal audit programs as significantly higher than for those facilities with effective internal audit programs.

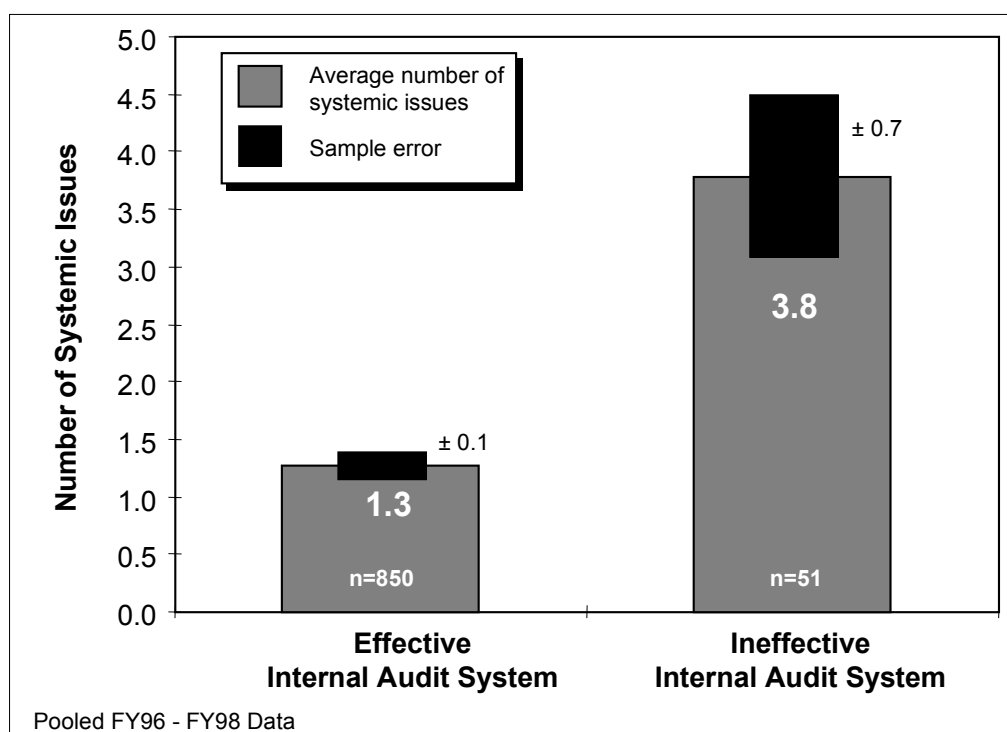


Figure 3-46.—Comparison of the number of systemic issues at facilities with effective and ineffective internal audit programs (all facilities).

¹⁴ In order to maintain analysis reliability of the chi-squared analysis, the systemic issues were divided into five levels: one, two, three, four or five, and six or more systemic issues. The mean and standard deviation of the actual number of issues other than within the Internal Audit subsystem were used for the Z-test and confidence intervals.

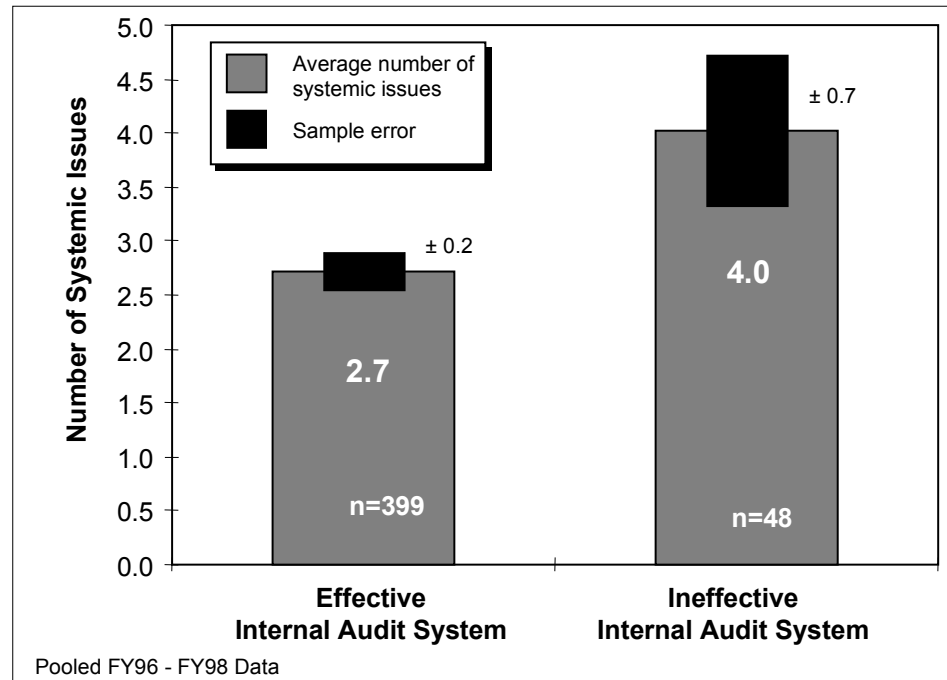


Figure 3-47.—Comparison of the number of systemic issues at facilities with effective and ineffective internal audit programs (facilities with at least one systemic issue in other than the internal audit subsystem).

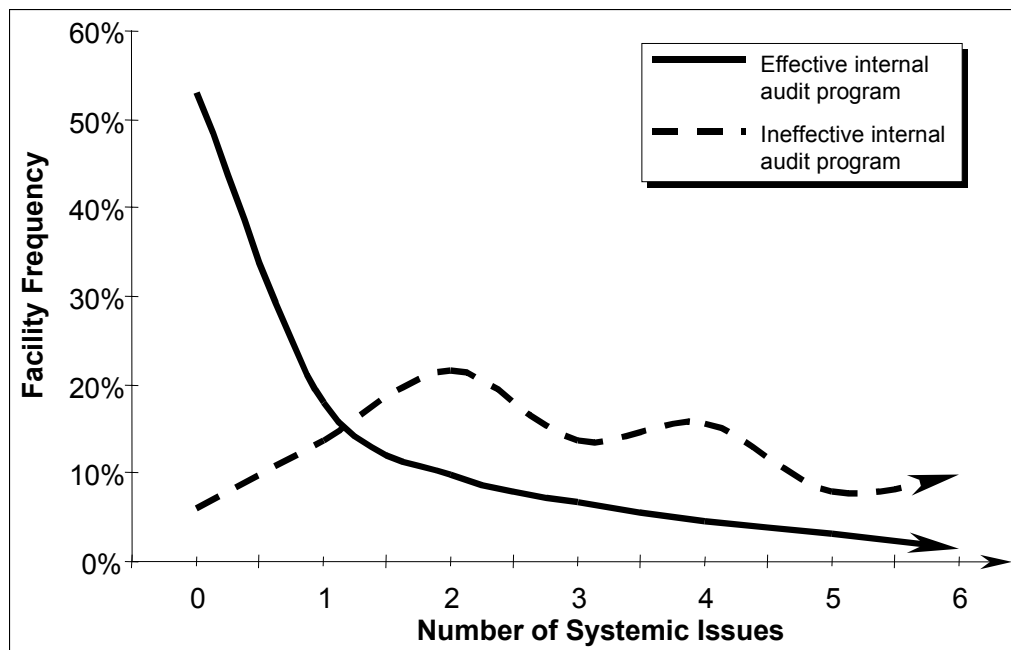


Figure 3-48.—Partial frequency distribution of facilities with systemic issues other than within the internal audit subsystem.

3.8.2 Does an Internal Audit Program Reduce Findings and Observations?

This year, sufficient data was collected to allow the comparison of facilities with and without internal audit programs in place. That analysis indicates that facilities with internal audit program had a lower probability of and fewer systemic issues of systemic issues (*figure 3-49 and figure 3-50 respectively*). The level at which findings and observations are reduced appears to depend upon the complexity of the facility and their documented quality control system. At small facilities with simple systems, there is little difference between those facilities with and without internal audit programs in place. However, as the facility increases in size and complexity, so to does the probability of findings and systemic observations for those facilities without an internal audit program.

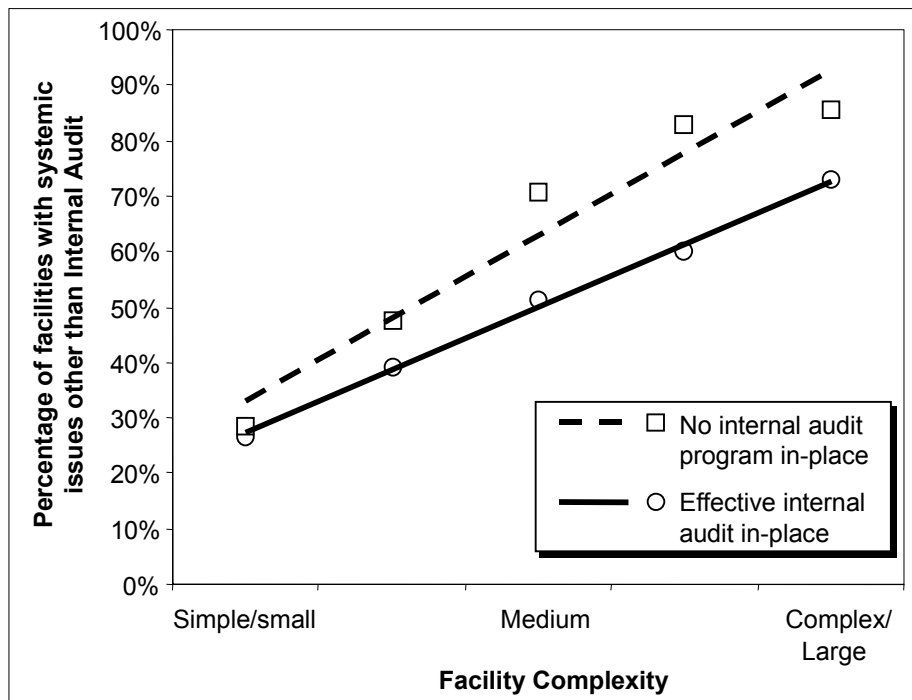


Figure 3-49.—The affect of an internal audit program on compliance.

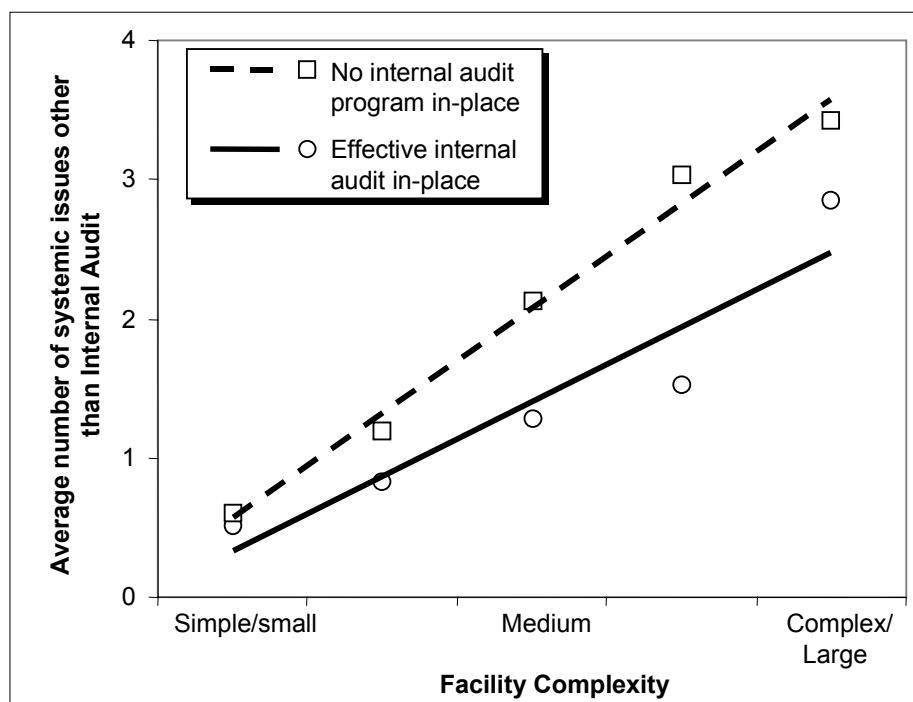


Figure 3-50.— The affect of an internal audit program on the number of findings and systemic observations.

Several factors could account for the affect that facility complexity has on the correlation of utilizing an internal audit program and the occurrence of findings and observations. First, an internal audit program could be an effective means of ensuring that process changes are documented in the procedures that are supposed to control those processes. In essence, internal audit could provide a systematic approach to process and procedural review. Another factor (assuming that internal audit is causing the difference in compliance) may be that larger and more complex facilities have more comprehensive internal audit programs in place. Current ACSEP evaluations do not assess the level nor the depth of implementation of internal audit programs. No distinction is made, for example, between a facility utilizing only statistical sampling on a small portion of their processes and that of a facility with a fully deployed, root-cause corrective action internal audit program with regular status reviews by upper management. A joint FAA and industry effort is presently underway to define what an internal audit program should look like (*Section 3.10* goes into more detail). The culmination of this effort should afford us a better opportunity to examine the factors that determine the effectiveness of an internal audit program.

Notwithstanding the above, this year's analysis has yielded a significantly better understanding of the relationship between internal audit and general procedural compliance.

3.9 Analysis of International Facilities

There were 43 ACSEP evaluations performed at international facilities. All 43 facilities were priority part suppliers.

The distribution of systemic issues for the international facilities, as shown in *figure 3-51*, is similar to that of domestic facilities (refer to *figure 3-3*). The ranking of issues among the various subsystems is very similar between domestic and international facilities.

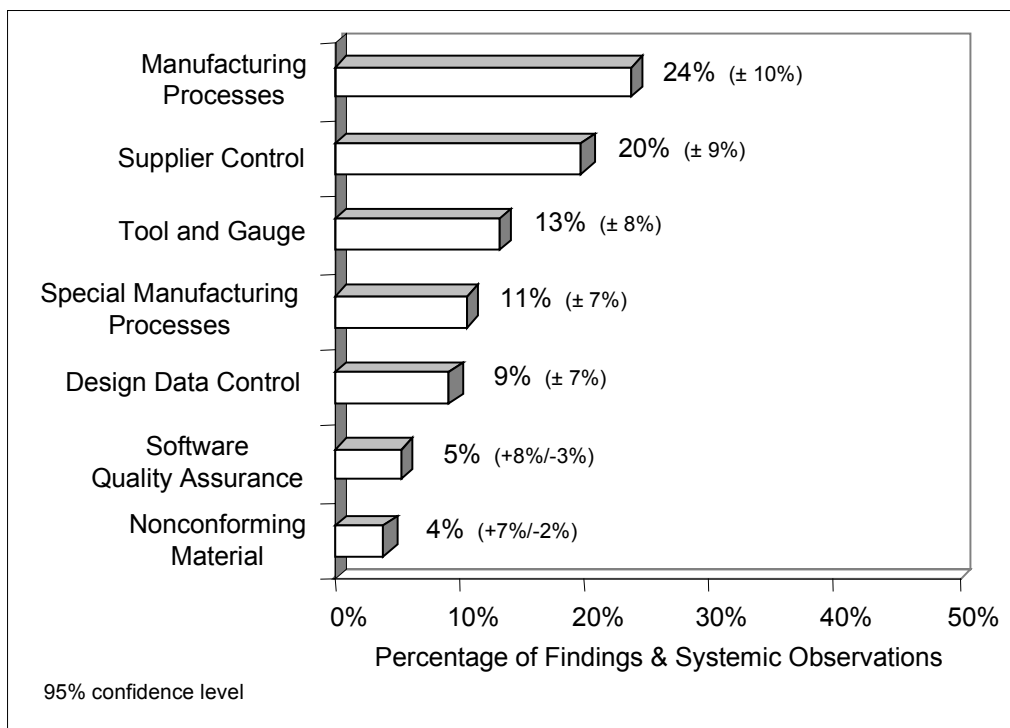


Figure 3-51.—Systemic issues — international facilities.

Figure 3-52 shows the proportion of facilities in which a systemic issue was recorded. The rate of occurrence of issues appears higher at international facilities than domestic facilities (refer to *figure 3-17*); however, this could be due to the low sample size not being representative of the whole population of facilities. Further analysis is not possible at this time due to the low volume of available data.

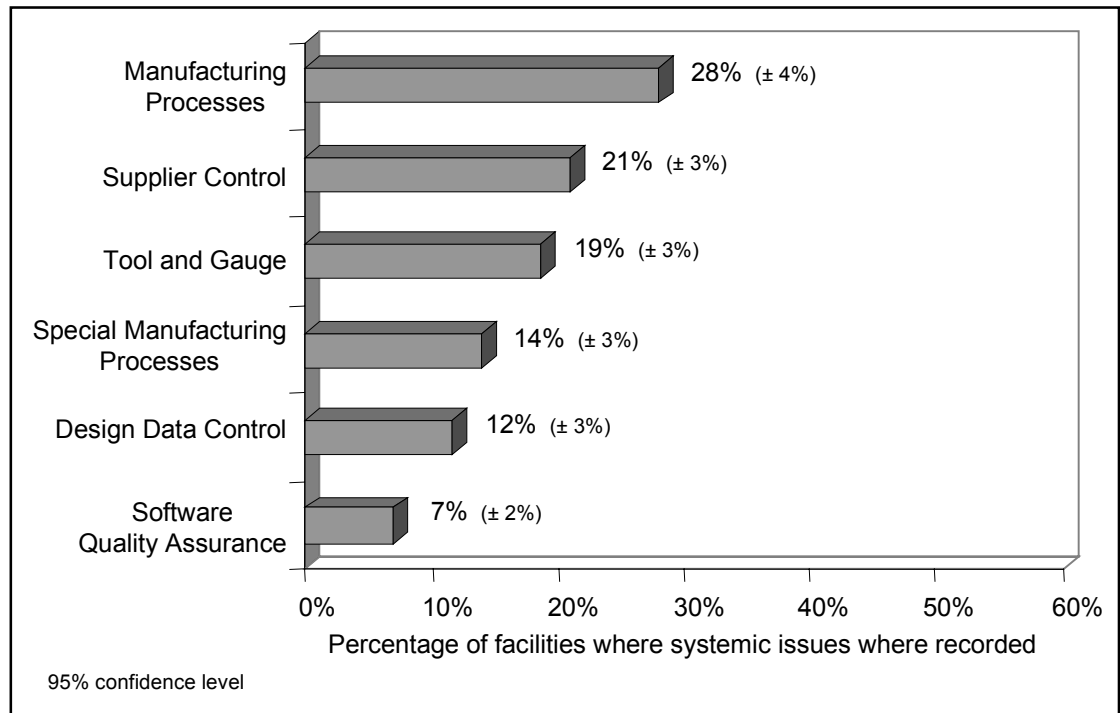


Figure 3-52.—Systemic issues — international facilities.

4. Data Analysis — Delegated Facilities

This is the first year data was collected for facilities with engineering delegation authority. Delegated facilities include Designated Alteration Stations (DAS), Special Federal Aviation Regulation No. 36 (SFAR-36) facilities, and Delegation Option Authorization (DOA) facilities. For the fiscal year, 37 systemic findings or systemic observations, 14 isolated observations, and 1 FAR-based observation were recorded. A summary for DAS and SFAR-36 facilities follows. As there was only one DOA facility evaluated in FY 1998 and only one finding and one isolated observation recorded, No separate summary for DOA facilities is presented in this section. The details of all the findings and observations are in *Section C2 of Appendix C*.

4.1 Designated Alteration Stations (DAS) Facilities

ACSEP evaluations were performed at 14 DAS facilities. The 27 systemic issues recorded during the year were recorded at 71 percent of the facilities evaluated. The following *figure 4-1* illustrates the three most prevalent subsystems with systemic issues. These issues account for 56 percent of all systemic issues recorded for DAS facilities. *Figure 4-2* illustrates the percentage of facilities that had systemic issues. Seven isolated observations were recorded at DAS facilities.

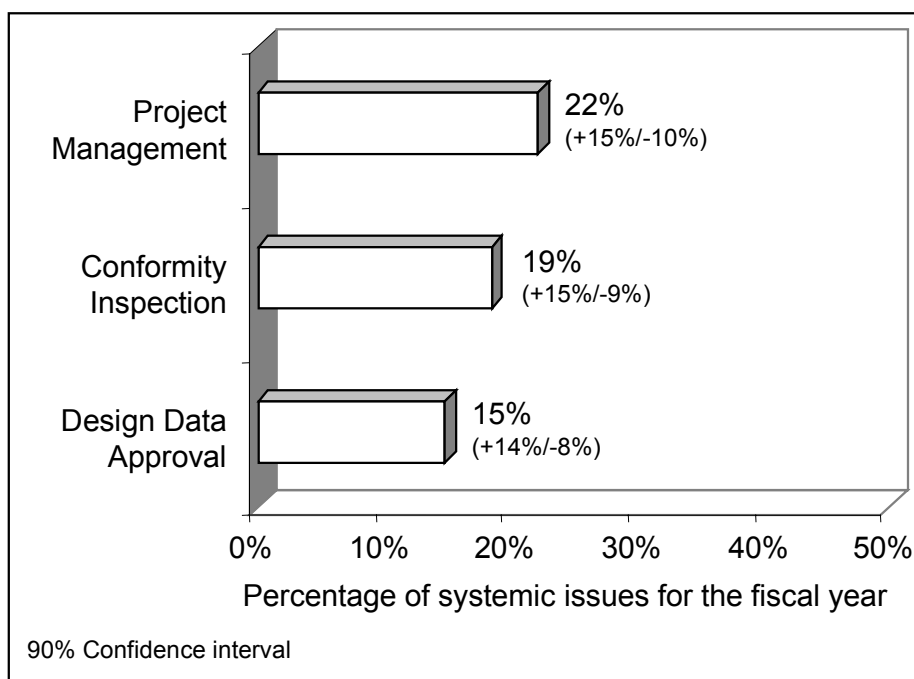


Figure 4-1.—Findings and systemic observations — DAS facilities.

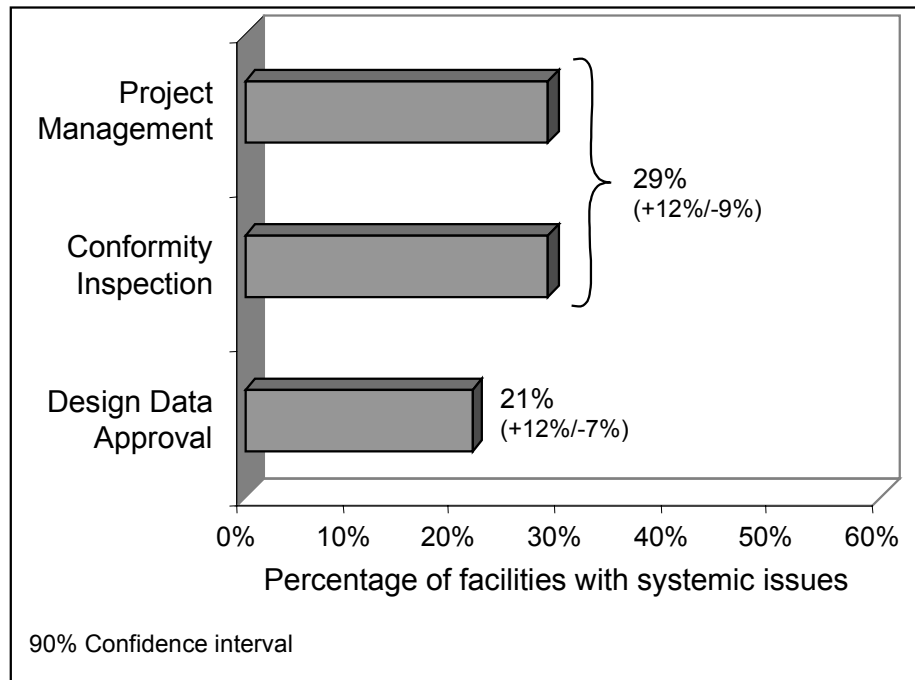


Figure 4-2.— Proportion of DAS facilities with Findings and systemic observations.

4.2 Special Federal Aviation Regulation No. 36 (SFAR-36) Facilities

ACSEP evaluations were performed at ten SFAR-36 facilities. The nine systemic issues recorded during the year were recorded at 40 percent of those facilities evaluated. The following *figure 4-1* illustrates the subsystems with systemic issues. *Figure 4-2* illustrates the distribution of the systemic issues among the facilities evaluated. Two isolated observations were recorded at separate SFAR-36 facilities. One FAR-based observation was also recorded during the year.

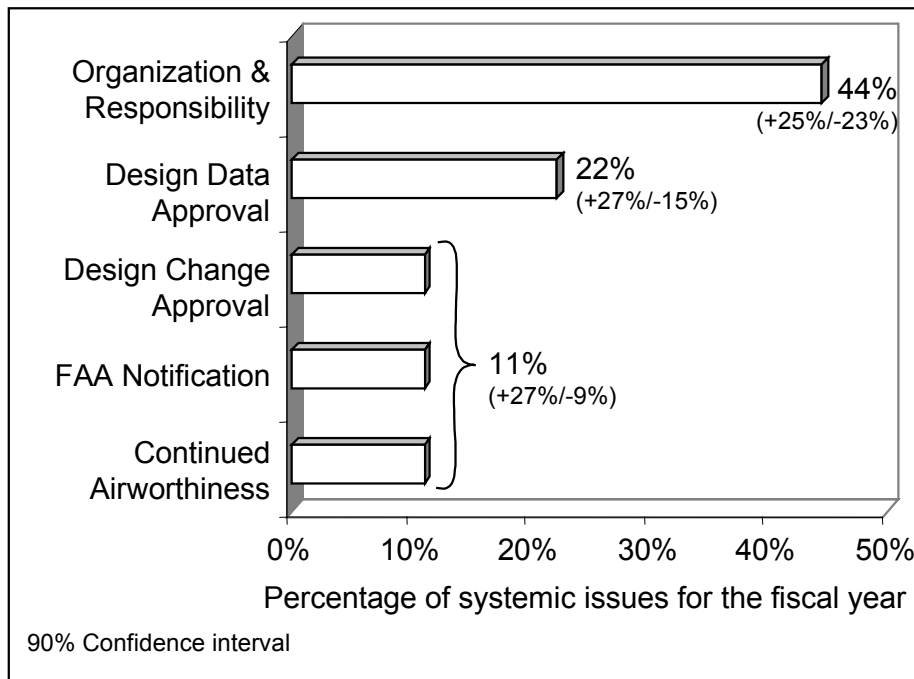


Figure 4-3.—Findings and systemic observations — DAS facilities

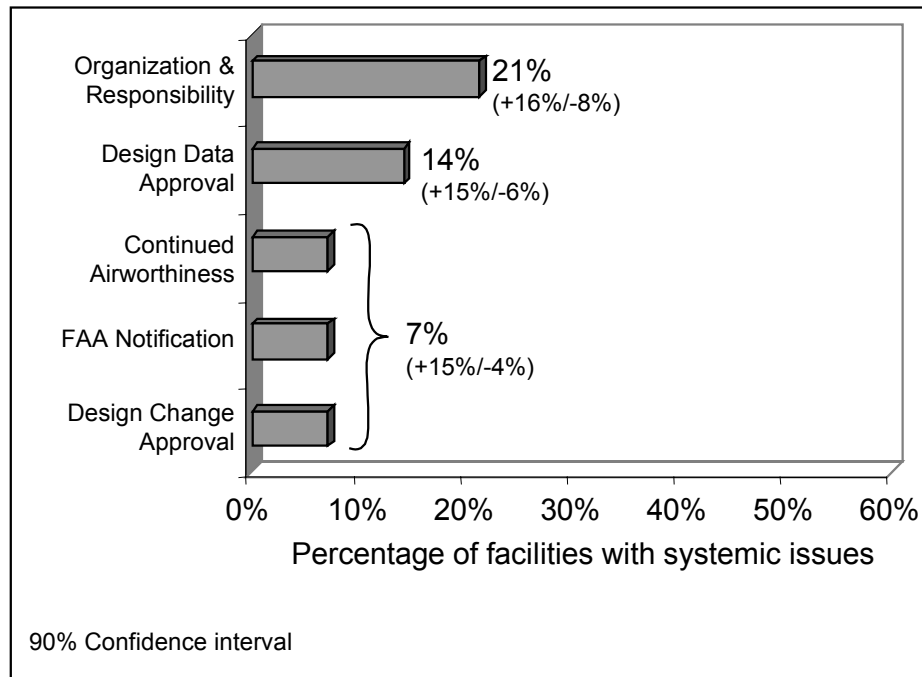


Figure 4-4.— Proportion of DAS facilities with Findings and systemic observations.

5. Significant Events During the Fiscal Year

Two events worthy of special note occurred during Fiscal Year 1998.

FAA Notice N8100.13 was issued incorporating delegated facilities into ACSEP. Delegated facilities include Delegation Option Authorization facilities (DOA), Designated Alteration Stations (DAS), and Special Federal Aviation Regulation No. 36 (SFAR-36) facilities. Delegated facilities were incorporated into ACSEP for the purpose of “determining that the design approval system in place at the delegated facility is producing a safe design and is in compliance with the airworthiness requirements.” The evaluation of delegated facilities differ from the evaluation of PAH’s. The ACSEP evaluation is based on a different set of evaluation systems and their associated criteria. For delegated facilities, a total of 10 system elements containing a total of 144 evaluation criteria are used. For PAH’s, a total of 17 system elements containing a total of 227 evaluation criteria are used. The evaluation criteria used for delegated facilities differs from that used for PAH’s because of the type of work performed at the facility types.

The second significant event was initiated at the October 1997 meeting between the FAA and the Manufacturing, Maintenance, & Repair Committee (MMRC) of the industry groups Aerospace Industries Association (AIA) and the General Aviation Manufacturers Association (GAMA). After an exchange of the ACSEP analysis results, the MMRC agreed to form two teams, in cooperation with the FAA, to attempt to formulate plans to reduce findings and observations. The two areas that will be focused on are supplier control and internal audit. The supplier control team will seek to develop a plan to reduce findings and observations in their supplier control processes. The internal audit team will attempt to define what internal audit programs might entail. The actions of these two teams are presently underway.

6. Improvement Emphasis

The goal of the ACSEP is to support continuing operational safety and promote continuous improvement.

6.1 Industry Feedback

As part of the ACSEP Quality Improvement Program, a performance feedback report (FAA ACSEP Evaluation Feedback Report) is provided to each evaluated organization when notified that an evaluation is scheduled to take place. Each facility evaluated is requested to use this report to critique the FAA ACSEP evaluation process. The feedback report is used to record the facility's impression for each step of the evaluation, from notification to the post-evaluation conference. A question concerning the professionalism of the ACSEP evaluation team is also included on the report. The facility's management is encouraged to complete the report and return it for analysis. Feedback reports were returned by 46 percent of the facilities, which is down from 56 percent the previous year.

The categories that industry was asked to grade during the first part of the FY 1998 ACSEP evaluation period, were the same as those used in previous years. A new set of categories (shown in *figure 6-4*) was introduced later within the FY98 period. The new categories were introduced to provide better insight into potential problem areas. Since the introduction was made in the middle of the FY 1998 ACSEP evaluation period, two analyses were performed.

One analysis used all of the feedback reports. Those reports that utilized the same grading method as previous years were used as is. Those reports that utilized the new grading method, had the responses grouped and averaged into groupings that matched those used for the previous years. The two sets of data were then combined to provide an overall base.

The second analysis was performed on only those reports that used the new categories.

Overall, the feedback was very good. Distribution of the data using both the old and new categories was consistent, with greater than 99 percent of the responses being "Satisfactory" or better. (See *figure 6-1* and *figure 6-2*). The Directorate Continuous Improvement Team (DCIT) will make the evaluators aware of the industry feedback that accounted for the very small percentage of "Poor" and "Unsatisfactory" responses. *Figure 6-3* and *figure 6-4* give the average scores for each of the feedback categories measured and an overall average. The data presented in *Figure 6-3* is consistent with the data from the last three fiscal years. The area with the lowest score was pre-evaluation arrangements. The data presented in *Figure 6-4* shows that the pre-evaluation arrangement score was most influenced by the feedback category of coordination/planning.

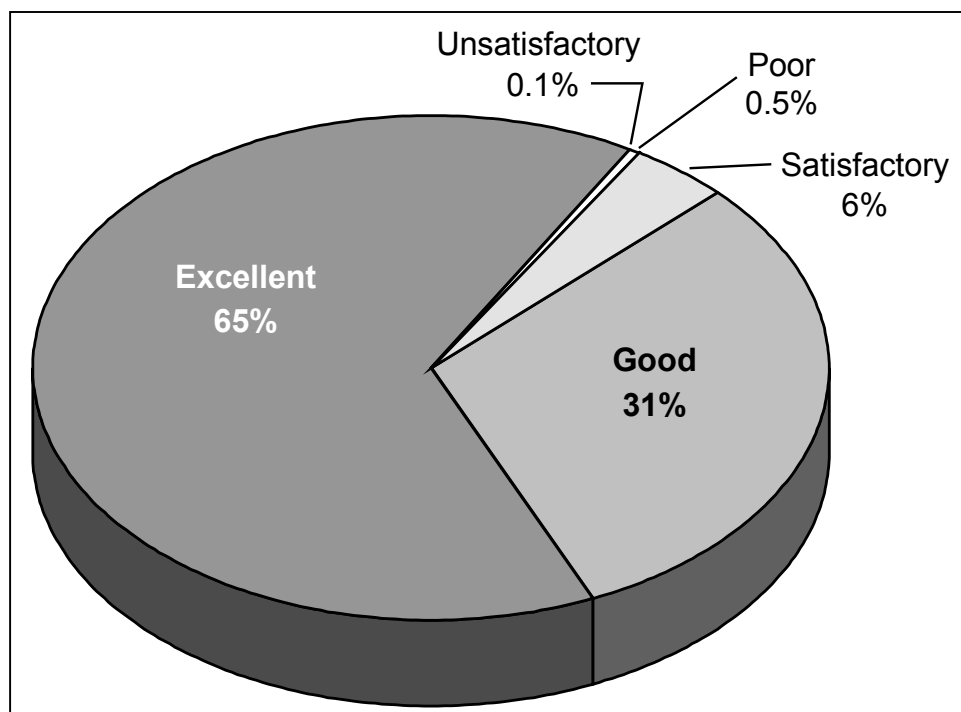


Figure 6-1.—Distribution of industry feedback using old categories.

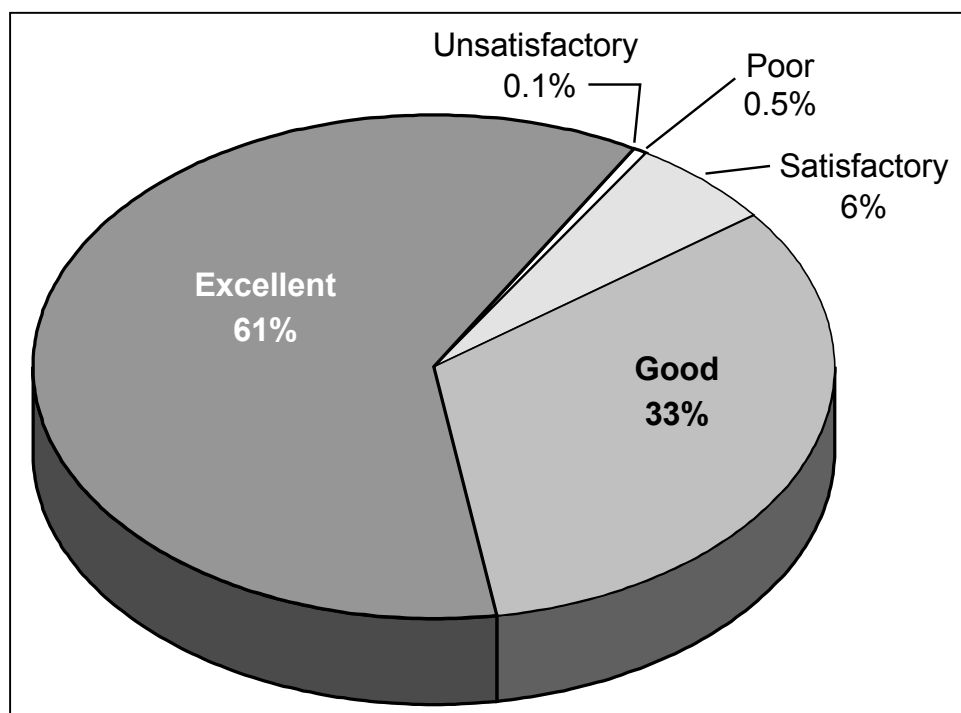


Figure 6-2.—Distribution of industry feedback using new categories.

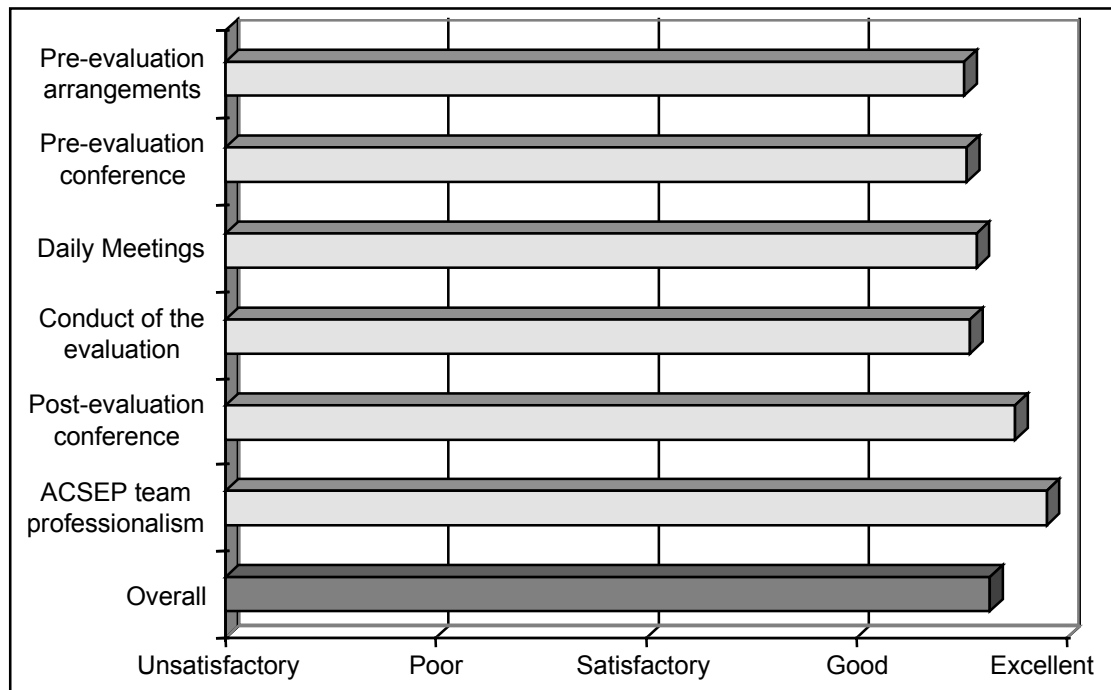


Figure 6-3.—ACSEP as graded by industry using old categories.

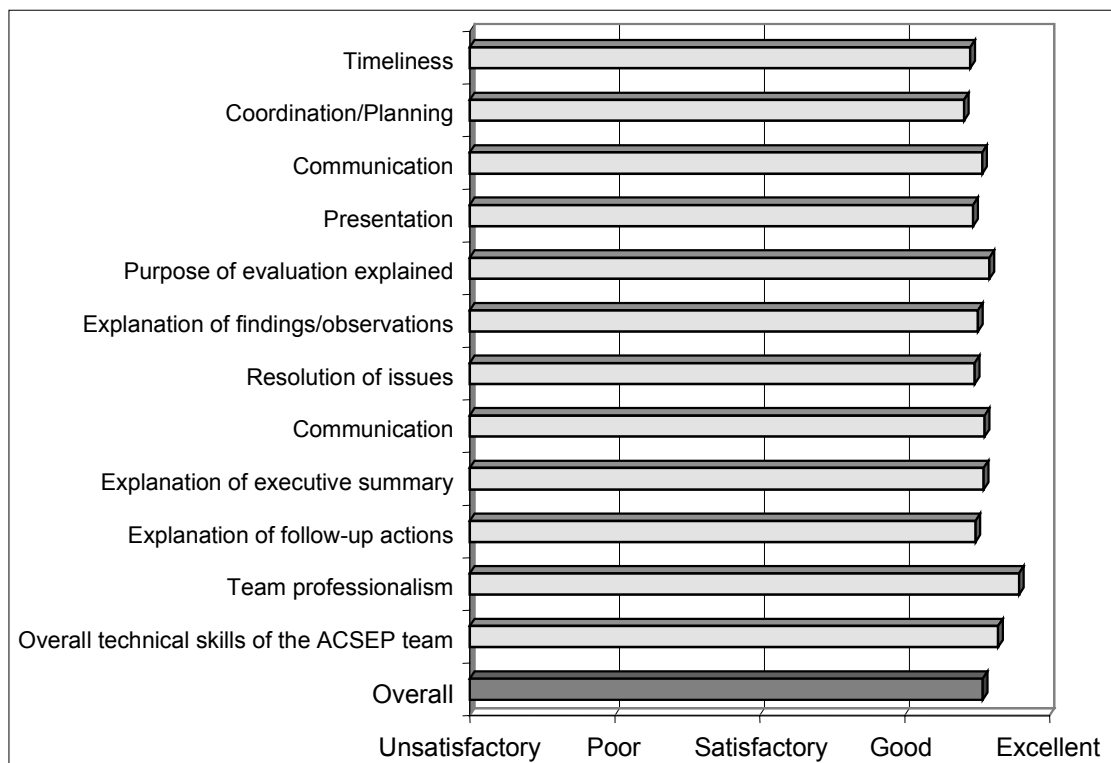


Figure 6-4.—ACSEP as graded by industry using new categories.

6.2 Lessons Learned

An additional part of the continuous improvement process is the gathering and analyzing of lessons learned that the evaluation team documented at the conclusion of each ACSEP evaluation. Each ACSEP evaluation team submits a “lessons learned” form that records the team’s general assessment of the evaluation, difficulties with the order, subsystems not evaluated, and any proposed new criteria. *Figure 6-5 through figure 6-8* show the trend in these lessons learned from FY 1994 to FY 1998.

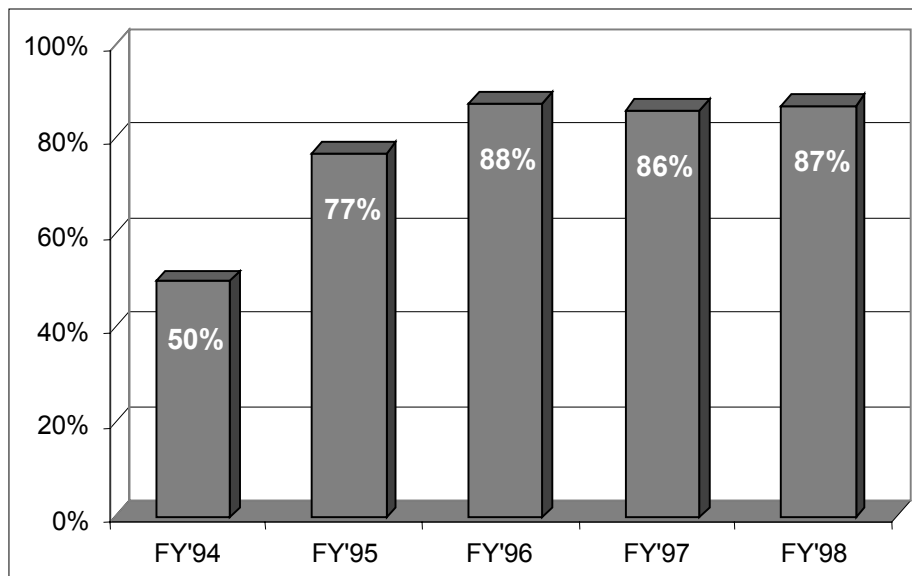


Figure 6-5.—Trend of lessons learned—favorable experiences.

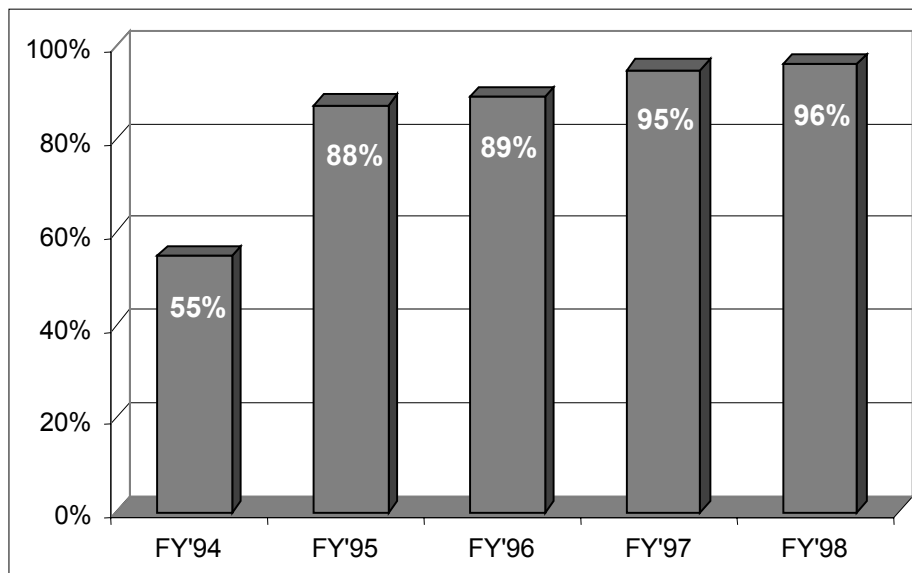


Figure 6-6.—Trend of lessons learned—no difficulties with Order 8100.7.

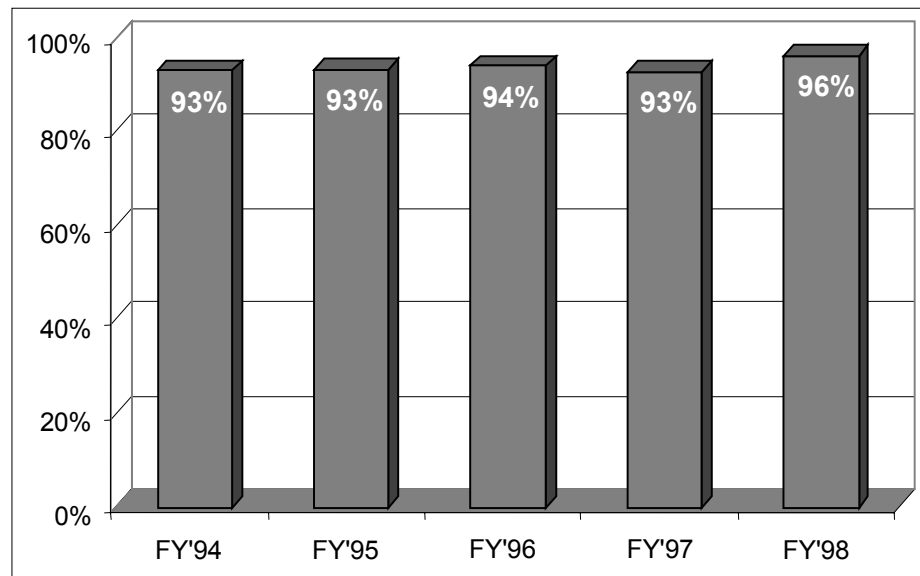


Figure 6-7.—Trend of lessons learned—evaluation completed.

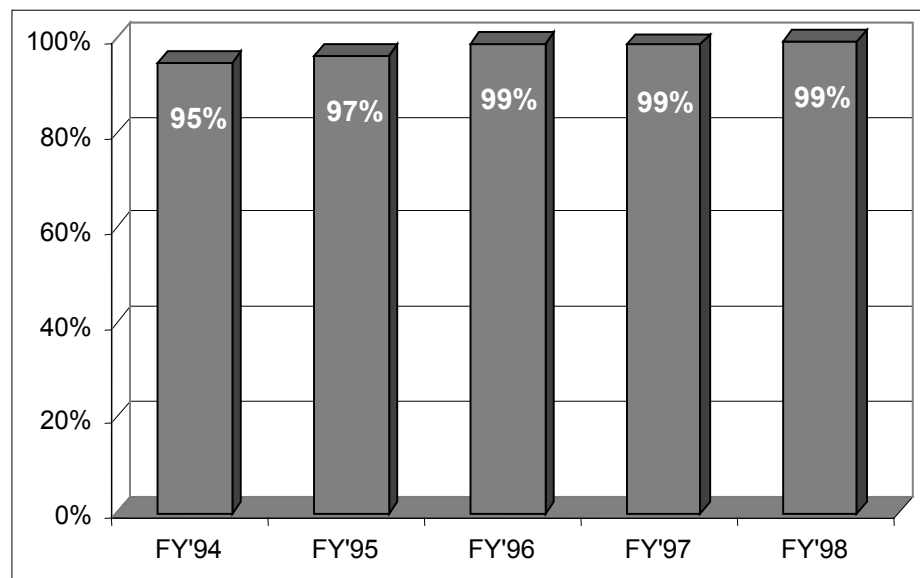


Figure 6-8.—Trend of lessons learned—no new criteria needed.

Only four percent of the teams had problems using Order 8100.7 to conduct the evaluations. This is consistent with the previous year. Also, less than one percent of the evaluation teams required the use of new criteria not already contained in the order. The percentage of teams reporting general issues and difficulties was also consistent with FY 1997 data.

As reported last year, analysis shows that issues and/or difficulties are twice as likely to occur during the evaluation of international facilities as during the evaluation of domestic facilities. (See *figure 6-9*). The most often cited issue was the presence of a language barrier, primarily in communicating with the facility escorts. The second most often cited cause of difficulty with evaluations at international facilities was the presence of cultural differences between the evaluation team and the personnel/management. In most of the reported cases of cultural differences causing an issue, adjustments were made by either the evaluation team or the facility personnel to accommodate the cultural diversity.

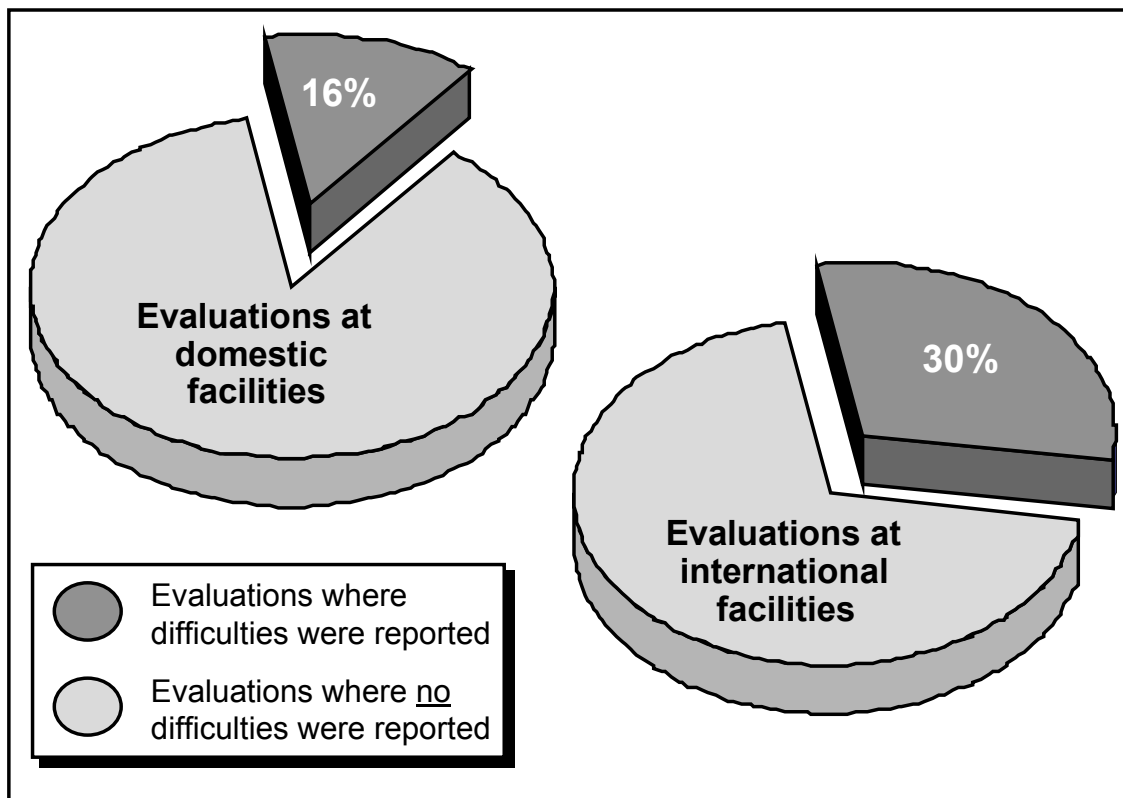


Figure 6-9. —Lessons learned – ACSEP evaluations at domestic vs. international facilities.

Figure 6-10 presents the number of ACSEPs with subsystems not completed. When compared to the FY 1997 data, the FY 1998 data indicate that team leaders have made an effort to ensure that prevalent subsystems identified in *Section 3.5* of the FY 1997 report were evaluated in FY 1998. Team leaders should continue to not defer an evaluation of any of the most prevalent subsystems unless there are very strong extenuating circumstances. This issue will continue to be stressed in future training programs.

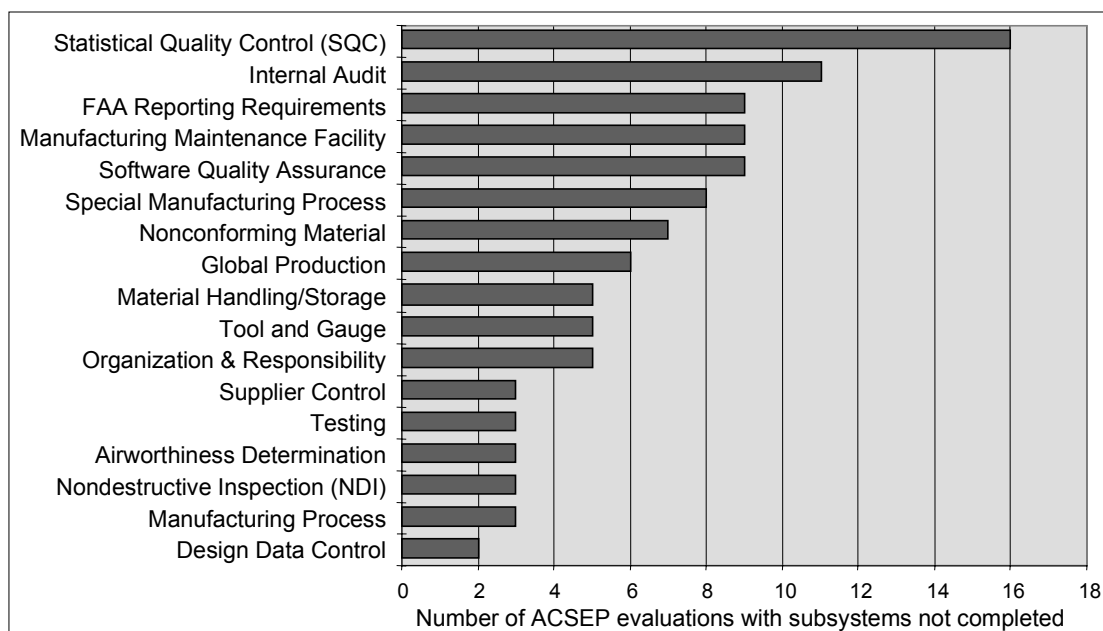


Figure 6-10.—Distribution of subsystems not evaluated.

Additionally, the decision of when to evaluate or not evaluate internal audit should be carefully considered in light of the conclusions presented in *Section 3.8* concerning internal audit. This analysis has shown that an internal audit system not in compliance with a facility's own procedures and policies is a strong predictor of additional systemic issues elsewhere within the facility. By performing an evaluation on a facility's internal audit program, the team leader will be provided with invaluable insight into the general compliance of the facility. Discovery of a discrepant internal audit program suggests that other issues may permeate the facility, i.e., what may appear on the surface to be an isolated issue could in reality be systemic in nature. However, team leaders are cautioned, once finding an internal audit system not in compliance, against focusing the evaluation with the purpose of accumulating findings and observations simply because their internal audit system was discrepant. Rather, the team leader should use this knowledge to gauge how deeply to investigate an isolated incidence of noncompliance to ensure it is not really a systemic issue. Because the Internal Audit subsystem is such a strong indicator of overall facility compliance, the maximum benefit from evaluating an internal audit system can be obtained if it is done early in the evaluation to afford enough time to use this information.

Table 6-1 presents a detailed breakdown of other comments received with the Lessons Learned. There was a notable increase in “Computers or ACSEP software issues” that can be attributed to a software change introduced during the FY 1998 evaluation period. The software change initially caused problems for the evaluators. Additional training has since been implemented to address this issue.

TABLE 6-1.—Comments received from lessons learned sheets

General Issues/Comments	FY'94	FY'95	FY'96	FY'97	FY'98
Time scheduled at facility was too short or too long	8%	5%	6%	5%	5%
Computer or ACSEP software issues	2%	3%	0%	0%	3%
Logistics; no escorts or QC mgr., facility not notified	3%	2%	0%	2%	1%
Language barriers	n/a	1%	0%	1%	1%
QC Manual: incomplete, outdated, conflicts with other procedures	3%	3%	1%	1%	0%
Production is very low, inactive, or inappropriate for audit	n/a	7%	2%	1%	0%
Management defensive/uncooperative	n/a	n/a	n/a	1%	0%
ISO 9000 certification better prepared the facilities for ACSEP evaluation	n/a	1%	1%	1%	0%
Recommend extending evaluation frequency	2%	1%	1%	1%	0%
Misc. other issues	3%	2%	2%	2%	3%
Difficulty with Order	FY'94	FY'95	FY'96	FY'97	FY'98
Criteria; add, incorrect, or subsystem issues	8%	6%	5%	4%	2%
ACSEP too big for facility	1%	2%	2%	0%	1%
Observations & findings; confusion with definitions	2%	1%	1%	0%	0%
Confusion with the application of 4's and 6's on Form 8100-4 ¹⁵	2%	1%	1%	0%	0%
Confusion about recording multiple occurrences of findings or observations	n/a	1%	1%	1%	0%
Flowchart in Appendix 8 is difficult to use ¹⁶	n/a	n/a	1%	0%	0%

¹⁵ As per Appendix 8 in Order 8100.7, a “4” is used to specify “criteria not in use” and a “6” is used to specify “not applicable.”

¹⁶ The flow chart is figure 1.—*Rating of subsystem evaluation criteria* presented in Appendix 8, *Preparation instructions for FAA Form 8100-4, ACSEP rating sheet* of Order 8100.7, Aircraft Certification Systems Evaluation Program.

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APPENDIX A

HISTORY AND BACKGROUND OF ACSEP

A1. Background

The ACSEP was developed as a result of numerous years of experience with Quality Assurance Systems Analysis Review (QASAR) audits and observations made during an interim audit program called “Operation SNAPSHOT”. Maintaining consistency with new FAA policies and regulations, with regards to the certificate management process, was also a consideration for the establishment of ACSEP. The intent was to establish a surveillance system that would meet the needs and requirements of the FAA and industry, while incorporating standardized evaluation practices and techniques consistent with the aircraft manufacturing environment and internationally recognized guidelines. The evaluation criteria were developed, in part, in conjunction with the Aerospace Industries Association and General Aviation Manufacturer's Association. By design, ACSEP will support continued operational safety in an ever changing aircraft manufacturing environment (e.g., new technologies, automation, and co-production) through recurring evaluations of facilities’ quality management systems and tracking and trending areas for improvement.

A2. Overview

ACSEP is an Aircraft Certification Service program. The Production and Airworthiness Certification Division, AIR-200, is the national focal point for the reporting of ACSEP evaluation results. Order 8100.7 and Notice N8100.13 provide guidance and assign responsibility for the implementation of the ACSEP and are vital tools in assurance of the FAA's mission of continued operational safety. The program assesses the compliance of PAH's, priority part suppliers, and delegated facilities to the requirements of applicable FAR and FAA-approved data, including compliance to the procedures established to meet those requirements. It also surveys the application of standardized evaluation criteria not required by the FAR to identify national trends that may require development of new or revised regulations, policy, and guidance.

Evaluation criteria for PAH's and priority part suppliers (manufacturing facilities) are divided into six major systems. The system elements vary in number of evaluation criteria assigned to them from a high side of 120 criteria — or 53 percent of the total — for the Quality System to a low side of 12 criteria — or 5 percent of the total — for the Management System (reference *figure A-1*).

The six major systems are:

- Management
- Engineering
- Manufacturing
- Quality
- Service/Product Support
- Communication with the FAA

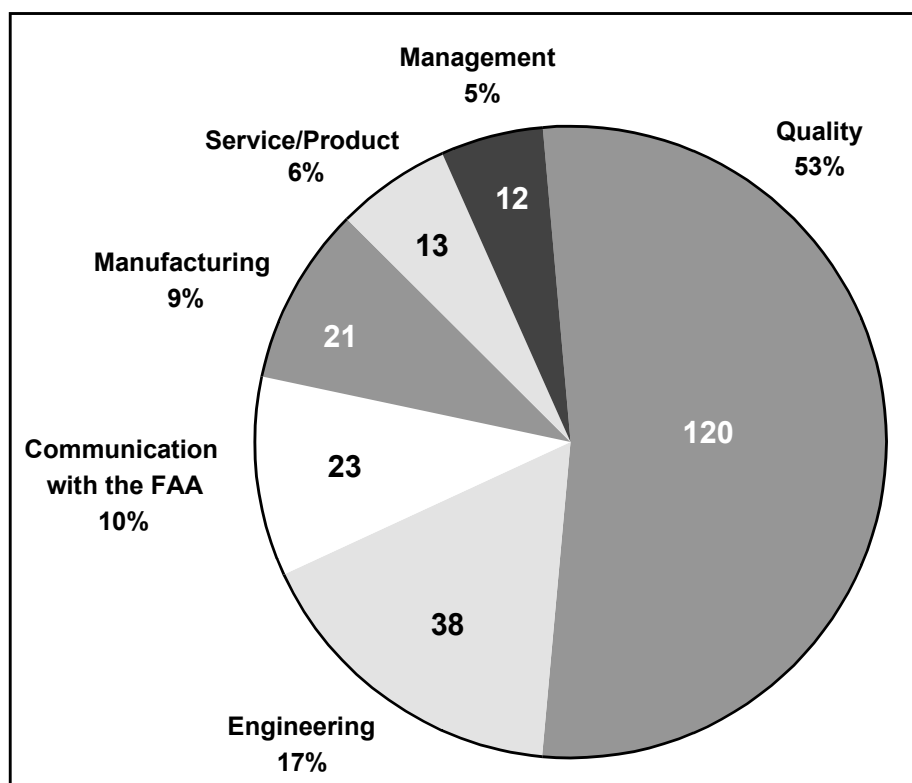


Figure A- 1.—Evaluation criteria distribution within the six major system elements of ACSEP.

The six system elements are further broken down into 17 subsystems for detailed data collection and reporting. The 17 subsystems are:

- Organization and Responsibility
- Design Data Control
- Software Quality Assurance
- Manufacturing Processes
- Special Manufacturing Processes
- Statistical Quality Control (SQC)
- Tool and Gauge
- Testing
- Nondestructive Inspection
- Supplier Control
- Nonconforming Material
- Material Handling/Storage
- Airworthiness Determination
- FAR Reporting Requirements
- Internal Audit
- Global Production
- Manufacturing Maintenance Facility

These system elements contain criteria that assess compliance to the various requirements of the FAR, FAA-approved data, and implementation of accepted industry practices. In total there are 227 evaluation criteria in the manufacturing portion of ACSEP. However, the number of evaluation criteria contained in these system elements varies and is not equally proportioned to each facility type. The amount of variation is due to the FAR requirements and industry practices for the different facility types. The 17 subsystems vary in proportion from a high side of 26 evaluation criteria or 12 percent of the total for

Manufacturing Processes to a low side of two evaluation criteria or 1 percent for Internal Audit (reference *figure A-2*).

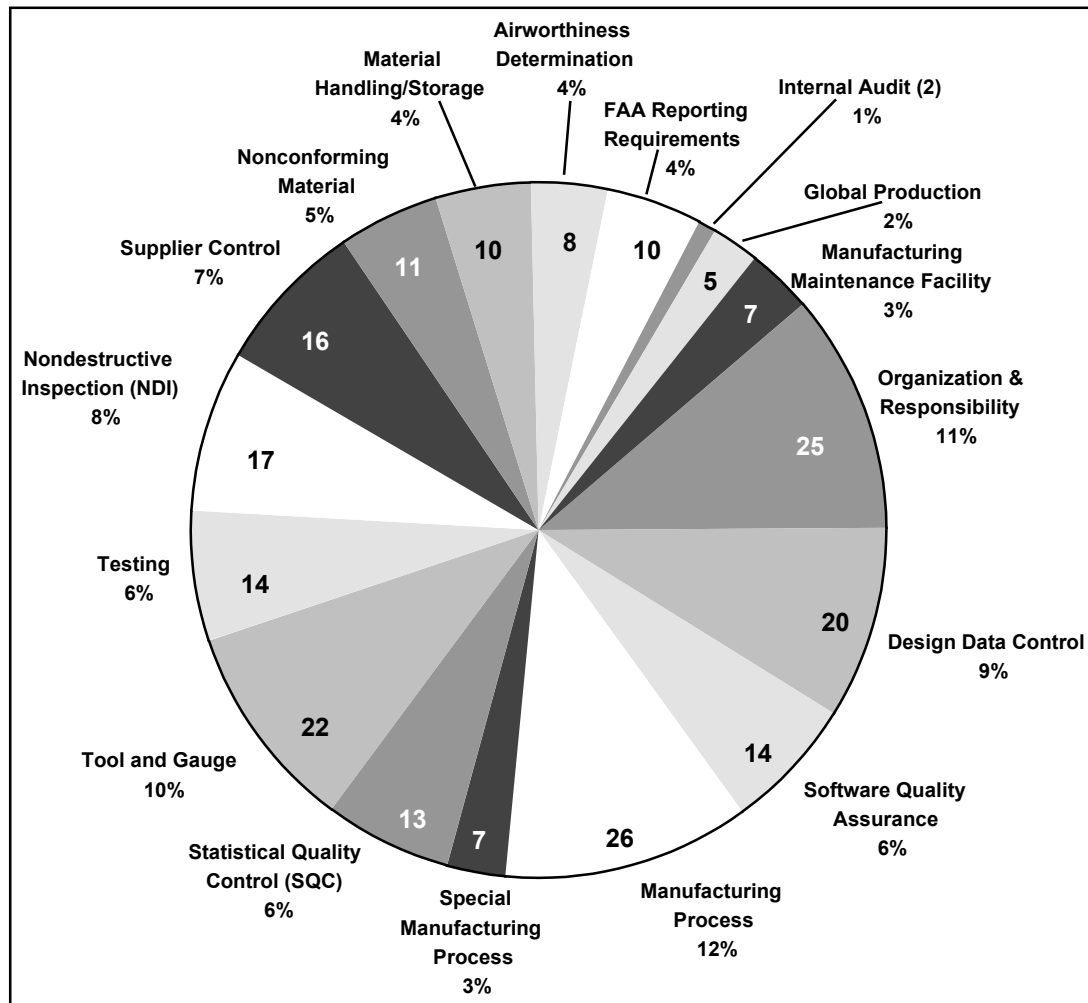


Figure A- 2. —Evaluation criteria distribution within the 17 subsystems of ACSEP for manufacturing facilities.

Evaluation criteria for delegated facilities are divided into ten system elements. The ten system elements are:

- Organization and Responsibility
- Design Data Approval
- Testing
- Airworthiness Certification
- Continued Airworthiness
- Project Management
- Design Change Approval
- Conformity Inspection
- FAA Notification
- Audit

Similar to the subsystems for PAH's, these system elements contain criteria that assess compliance to the various requirements of the FAR, FAA-approved data, and implementation of accepted industry practices. In total there are 114 evaluation criteria in the delegated facility portion of ACSEP. However, the number of evaluation criteria contained in these system elements varies. The amount of variation is due to the FAR requirements and industry practices. The 10 system elements vary in proportion from a high side of 27 evaluation criteria or 23 percent of the total for Project Management to a low side of 4 evaluation criteria or 4 percent for Audit and FAA Notification (reference *figure A-3*).

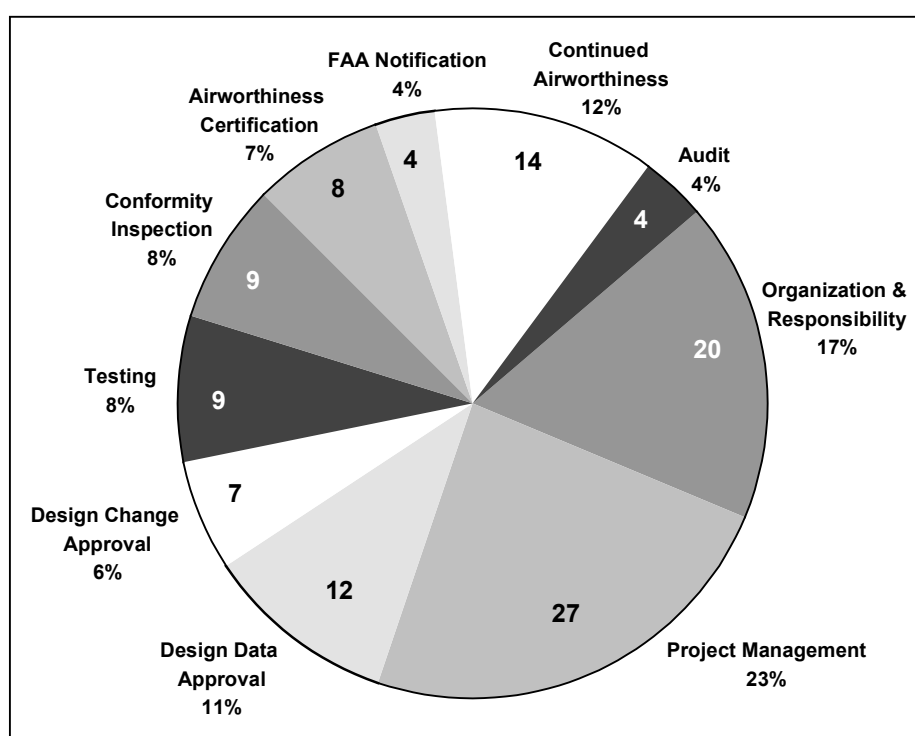


Figure A- 3. —Evaluation criteria distribution within the 10 subsystems of ACSEP for Delegated Facilities.

A3. Evaluations and Evaluators

The ACSEP utilizes teams of FAA engineering, flight test, and manufacturing inspection personnel to evaluate PAH's, their priority part suppliers, and delegated facilities. Upon completion of each ACSEP evaluation, the team leader prepares a report and forwards it to the Certificate Management Office (Manufacturing Inspection Office or Aircraft Certification Office, as applicable) which provides it to the Aviation Safety Inspector (ASI) and/or the Assigned Engineer (AE) responsible for the evaluated facility. A copy of the report is also provided to AIR-200 for entry into the ACSEP database. The ACSEP database contains administrative information on facilities evaluated, status of qualified

team members and team leaders, responses to rating criteria contained in the evaluation subsystem elements, along with findings and observations noted. Additionally, the ACSEP Master Schedule, which is prepared annually, is maintained by AIR-200 together with the Directorate coordinators. The scheduling database is updated and posted to a Service wide electronic mail bulletin board on a monthly basis ensuring the Aircraft Certification Service offices are kept current of ACSEP evaluation cancellations, date changes, and recent additions.

The facilities are categorized into two evaluation frequencies, 24 and 48 months. The 24-month frequency includes PAH's, delegated facilities, and priority parts suppliers. The 48-month frequency covers PMA's that produce non-priority parts. The evaluation frequency may be increased based on the type of PAH, system capability, evaluation results, and the guidelines in FAA Order 8100.7 and Notice N8100.13. Evaluation frequencies may also be shortened to the extent necessary to obtain confidence that the facility is complying with applicable FAR. The directorates, based upon facility performance, make these decisions.

At the conclusion of an ACSEP evaluation, a post-evaluation conference is held with the evaluated facility management, and any issues, findings, and/or observations are reviewed. The ASI and/or AE responsible for facility surveillance pursue any findings that require formal corrective action. The ASI and/or AE inform the facility of the findings and requests corrective action through a Letter of Investigation, when deemed appropriate. The ASI and/or AE track corrective action until closure on FAA Form 8100-5, Results of ACSEP Evaluation Findings.

The ACSEP also includes a Quality Improvement Program. Data from the evaluation feedback reports and evaluation reports are used to prompt improvements in the program. Continuous improvement teams established in each directorate and in the headquarters office review suggestions, comments, and results of the evaluations. The directorate teams act upon improvements that can be implemented locally; improvements that affect the national program are referred to a dedicated National Continuous Improvement Team (NCIT) made up of FAA Aviation Safety Inspectors, Aerospace Engineers, and Flight Test Pilots representing the directorates and headquarters. Managers representing the Aircraft Certification Management Team (ACMT), Aircraft Certification Office Management Team (ACOMT), and Manufacturing Inspection Management Team (MIMT) are also members of the NCIT. After a comprehensive review of the data, the NCIT then recommends changes or clarification to current policy. Recommended changes are forwarded to the Aircraft Engineering Division (AIR-100) or the Production and Airworthiness Certification Division (AIR-200) for further review and possible implementation.

The AIR organization is responsible for conducting evaluator training. This is accomplished in association with the FAA Academy with AIR-200 providing instructors. These instructors are experienced national evaluation team leaders who bring real life

experiences into the classroom. While one instructor presents the course materials, the other critiques the presentation/materials and notes comments from students. The critique and notes are reviewed and improvements incorporated facilitating a continuous improvement process. Additionally, issues found in the field are also integrated into the course making it even more comprehensive and continuously improving.

APPENDIX B

DEFINITIONS

Approved Production Inspection System (APIS) – Federal Aviation Administration (FAA) production approval issued to a manufacturer of an aircraft, aircraft engine, or propeller being manufactured under a type certificate only.

Assigned Engineer – An FAA engineer to whom the Aircraft Certification Office manager has assigned responsibility relating to ACSEP evaluations at a particular design approval facility.

Compliance – for the purposes of this report, compliance refers to a facility's business practices being consistent with published procedures and/or policies. These procedures/policies include: internal procedures/policies not requiring FAA approval, FAA-approved data, and the FAR.

Compliance Rate – the proportion of facilities whose business practices were found to be in compliance with published procedures and/or policies at the time of an ACSEP evaluation. These procedures/policies include: internal procedures/policies not requiring FAA approval, FAA-approved data, and the FAR.

Criteria – the basic element of an ACSEP evaluation. Criteria are used to plan the depth of the evaluation and to document the results of the evaluation in a standardized manner. The criteria are grouped into systems and subsystems.

Delegated Facility – a facility undertaking DOA, DAS, or SFAR-36 activity.

Delegation Option Authorization (DOA) – an organization or facility authorized by the FAA to accomplish type, production, and airworthiness certification of certain products as specified in FAR § 21.231(a).

Designated Alteration Station (DAS) – an organization or facility authorized by the FAA to issue supplemental type certifications, experimental certificates, and amended standard airworthiness certificates in accordance with its FAA-approved procedures manual.

Established Industry Practice – a widely followed method of operating that achieves consistent performance of specific functions (i.e., calibration recall system, internal audit system, and statistical process control).

Facility – for this report, any production approval holder or priority part supplier.

FAR-based Observation – an occurrence of FAA-approved data not in compliance to the FAR.

Federal Aviation Regulations (FAR) – regulations listed in Title 14 (Aeronautics and Space) of the Code of Federal Regulations (CFR).

Finding – systemic noncompliance to the FAR, FAA-approved data (or in the case of supplier facilities, the purchasing instrument), or a safety-related noncompliance.

Issue – An inconsistency between the actual operating practices of a facility and the FAR, FAA-approved data, or the facility's internal procedures.

Isolated Observation – isolated occurrence of noncompliance to the FAR or FAA-approved data.

Manufacturer's Maintenance Facility (MMF) – defined by FAR § 145.1(c) as a repair station certificate with a limited rating issued to a manufacturer based upon the Production Approval it holds from the FAA.

National Continuous Improvement Team (NCIT) – a dedicated national team of FAA Aviation Safety Inspectors, Aerospace Engineers, Flight Test Pilots, and managers representing the Directorates and Divisions chartered to review the ACSEP periodically for areas of improvement.

Noncompliance – for the purposes of this report, noncompliance refers to a facility's business practices being inconsistent with published procedures and policies at the time of the ACSEP evaluation. These procedures and/or policies include: internal procedures/policies not requiring FAA approval, FAA-approved data, and the FAR.

Noncompliance Rate – the proportion of facilities where at least one business practice was inconsistent with published procedures or policies, or any portion thereof, at the time of the ACSEP evaluation. These procedures and/or policies include: internal procedures not requiring FAA approval, FAA-approved data, and the FAR.

Nonobservance – a failure to comply with self-imposed procedures that are related to, but not required by, the applicable production approval, delegated facility approval, or quality requirements from a parent manufacturing maintenance facility.

Parts Manufacturer Approval (PMA) – an FAA production and design approval issued to manufacturers who produce replacement or modification parts, equipment, components, materials, part processes (replacement and modification, and appliances).

Principal Inspector (PI) – an FAA Aviation Safety Inspector who has been assigned certificate management and/or surveillance responsibility for a PAH, associate facility, or priority part supplier.

Priority Part Supplier (PPS) – any person or organization (including a distributor) that furnishes priority parts (as defined in Order 8120.2A) to a PAH.

Production Approval Holder (PAH) – the holder of a Production Certificate, APIS, PMA, or Technical Standard Order (TSO) authorization, who controls the design and quality of a product or part thereof.

Production Certificate (PC) – an FAA production approval issued to a manufacturer of aircraft, aircraft engines, or propellers that has had its Quality Control system examined and approved by the FAA, and that holds one or more of the following: a current type certificate; rights to the benefits of a type certificate under a licensing agreement; or a supplemental type certificate.

Production Certificate Extension (PCEX) – an FAA-approved extension of a specific manufacturer's PC to another facility.

Safety Finding – safety-related noncompliance that requires immediate action.

Special Federal Aviation Regulation No. 36 (SFAR-36) – an organization or facility authorized by the FAA to approve major repairs on a product or article in accordance with its FAA-approved procedures manual.

Subsystem – a logical grouping of several criteria into functional areas. There are 17 subsystems within ACSEP.

System – the highest level of grouping for the ACSEP criteria. Systems comprise the individual disciplines under which the criteria fall. There are six systems: Management, Engineering, Manufacturing, Quality, Service/Product Support, and Communication with the FAA.

Systemic Observation – systemic nonobservance to other than FAA requirements or FAA-approved data.

Technical Standard Order (TSO) authorization— an FAA design and production approval issued to a manufacturer for an article which has been found to meet a specific FAA Technical Standard Order.

APPENDIX C

CRITERIA HAVING FINDINGS OR OBSERVATIONS

C1. Manufacturing Facilities

This section provides the data collected during FY 1998 ACSEP evaluations conducted at PAH and priority part supplier facilities. *Tables C-1 through C-13* present data only from domestic facilities. The first three of these tables (*Tables C-1 to C-3*) present data for all facility types combined. The ten tables following (*Tables C-4 through C-13*) present data for the particular facility type specified. *Tables C-14 and C-15* present data from the international priority part suppliers.

The column titled “Percent of Applicable Facilities with Issues” provides the frequency of findings and/or observations being reported at those facilities where the criteria was implemented or applicable. This column of data can be used to gauge the significance of the issues at those facilities where the capability for the criteria was implemented — a facility focus as described in *Subsection 3.6.2*. In contrast, the table column titled “Percent of Facilities” (percent of all domestic facilities for *Tables C-1 through C-3* or percent of the domestic facilities within a particular facility type for *Tables C-4 through C-13* or percent of all international facilities for *Tables C-14 and C-15*) presents the frequency of facilities evaluated that had a noncompliance/nonobservance reported within the criteria. This column can be used to gauge the importance of the criteria as it affects the industry as a whole — as described in *Subsection 3.6.1*.

TABLE C- 1.—Systemic findings and observations

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Total Systemic Findings and Observations	Percent of Facilities	Percent of Applicable Facilities with Issues
1	10Q1	Initial & periodic evaluations of suppliers	34	5%	6%	8%
2	4P9	Completed product/part identification	33	5%	6%	6%
3	15M1	Internal auditing program	29	5%	5%	8%
4	12Q5	Identification of age control products	27	4%	5%	7%
5	10Q5	Flow down of technical & quality requirements	20	3%	4%	5%
6	4P4	Work instructions control manufacturing processes	18	3%	3%	4%
7	11Q1	Control of nonconforming products	18	3%	3%	4%
8	5Q3	Accord with process specifications	17	3%	3%	6%
9	11Q2	Permanent identification of scrap material	17	3%	3%	4%
10	7Q1	Approval/inspection of tools & gauges	17	3%	3%	3%
11	4Q5	Inspection records	17	3%	3%	3%
12	4Q1	Inspection methods and plans	16	3%	3%	3%
13	4Q12	Completion of all inspections & tests	15	2%	3%	3%
14	10Q8	Verification of raw material	14	2%	3%	3%
15	10Q10	Receiving inspection	14	2%	3%	3%
16	2E2	Drawing control system	12	2%	2%	2%
17	7Q3	Tool & gauge recall system	11	2%	2%	2%
18	2E7	Design/Technical data document control	11	2%	2%	2%
19	10Q2	Use of approved suppliers	11	2%	2%	2%
20	2C1	Minor design change approval	10	2%	2%	3%
21	4P3	Work instructions reflect tech data	10	2%	2%	2%
22	8E1	Test procedures/instructions established	8	1%	1%	2%
23	4M1	Operation within production limitations	8	1%	1%	2%
24	12Q3	Storage of conforming parts	8	1%	1%	2%
25	5Q4	Records maintained	7	1%	1%	3%

TABLE C- 1.—Systemic findings and observations—Continued

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Total Systemic Findings and Observations	Percent of Facilities	Percent of Applicable Facilities with Issues
26	14C3	Submittal of quality system data changes	7	1%	1%	2%
27	11Q4	Material review record generated	7	1%	1%	2%
28	4P2	Work instructions prepared	7	1%	1%	1%
29	2C4	Data submittal for TSO minor changes	6	1%	1%	5%
30	5Q2	Required qualifications/approvals	6	1%	1%	2%
31	7Q16	Inaccurate tools & gauges identified	6	1%	1%	1%
32	4Q3	Issuance of inspection stamps	6	1%	1%	1%
33	2E1	Design change approval	6	1%	1%	1%
34	1Q4	Quality Manual	6	1%	1%	1%
35	11Q3	MRB established and operational	5	1%	1%	1%
36	7Q14	Identification of gauges	5	1%	1%	1%
37	1Q5	Tags, forms, etc., described	5	1%	1%	1%
38	7Q11	Control of production tooling	4	1%	1%	1%
39	7Q2	Instructions for acceptance tooling	4	1%	1%	1%
40	11Q6	Corrective action required	4	1%	1%	1%
44	10Q12	Records of receiving inspection	4	1%	1%	1%
44	12Q8	Conforming products packaged & shipped	4	1%	1%	1%
45	2E6	Storage of design documents	4	1%	1%	1%
45	4E1	Accord with FAA-approved design data	4	1%	1%	1%
46	1Q6	Record retention schedule	4	1%	1%	1%
47	9Q14	Critical penetrant parameters identified	3	0.5%	1%	2%
48	10Q3	Approval of supplier quality manual	3	0.5%	1%	1%
49	5Q1	Equipment available & calibrated	3	0.5%	1%	1%
50	14C4	Relocation of manufacturing facility	3	0.5%	1%	1%
51	12Q2	Special environmental controls	3	0.5%	1%	1%
52	4E2	New/changed process test substantiation	3	0.5%	1%	1%
53	14C1	Failure reporting	3	0.5%	1%	1%
54	11Q7	Corrective action monitored	3	0.5%	1%	1%
55	10Q6	Quality Assurance review of purchase documents	3	0.5%	1%	1%
56	4P5	Work instruction revision approval	3	0.5%	1%	1%

TABLE C- 1.—Systemic findings and observations—Continued

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Total Systemic Findings and Observations	Percent of Facilities	Percent of Applicable Facilities with Issues
57	4P1	Change approval	3	0.5%	1%	1%
58	2E3	Technical data change approval	3	0.5%	1%	1%
59	7Q12	Calibration records	3	0.5%	1%	1%
60	12Q4	Segregation of product in storage	3	0.5%	1%	1%
61	17Q6	Completion of all requirements	2	0.3%	0.4%	3%
62	17Q4	Mechanics/repairmen directly in charge	2	0.3%	0.4%	3%
63	9Q4	Tanks & solutions checked	2	0.3%	0.4%	2%
64	16Q3	Export airworthiness approvals obtained	2	0.3%	0.4%	1%
65	9Q9	Records of compliance	2	0.3%	0.4%	1%
66	9Q3	NDI procedures/specifications available & used	2	0.3%	0.4%	1%
67	8Q3	Records of completed tests	2	0.3%	0.4%	1%
68	4P8	Traceability for split lots	2	0.3%	0.4%	1%
69	10E1	Control of supplier design and changes	2	0.3%	0.4%	1%
70	8E2	Control of test procedure/instruction changes	2	0.3%	0.4%	1%
71	15M2	Feedback to higher-level management	2	0.3%	0.4%	1%
72	1P3	Manufacturing staff qualifications	2	0.3%	0.4%	1%
73	7Q13	Adjustment of calibration intervals	2	0.3%	0.4%	0.5%
74	1Q3	Quality Assurance staff qualifications	2	0.3%	0.4%	0.5%
75	4Q9	Traceability to raw material	2	0.3%	0.4%	0.4%
76	2E9	Technical data file	2	0.3%	0.4%	0.4%
77	4Q10	Inspection marking	2	0.3%	0.4%	0.4%
78	4P6	Familiarity with specifications	2	0.3%	0.4%	0.4%
79	13Q2	Airworthiness certificates/special flight permits	1	0.2%	0.2%	5%
80	9Q15	Critical eddy current parameters identified	1	0.2%	0.2%	3%
81	8C3	Approval of test cell correlation/calibration standard	1	0.2%	0.2%	3%
82	3AE4	Recall/purge of obsolete software	1	0.2%	0.2%	3%
83	16Q2	Control of parts from associated facilities	1	0.2%	0.2%	3%
84	3AE5	Software security	1	0.2%	0.2%	2%

TABLE C- 1.—Systemic findings and observations—Continued

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Total Systemic Findings and Observations	Percent of Facilities	Percent of Applicable Facilities with Issues
85	3AP1	Software identification	1	0.2%	0.2%	2%
86	17Q2	Operation within certificate privileges	1	0.2%	0.2%	1%
87	17Q3	Work in accordance with Part 43 requirements	1	0.2%	0.2%	1%
87	17Q5	Record of completed work	1	0.2%	0.2%	1%
88	3BE1	Software Configuration Management Plan	1	0.2%	0.2%	1%
89	3BQ1	Verification prior to use	1	0.2%	0.2%	1%
90	6Q10	Corrective action	1	0.2%	0.2%	1%
91	9E2	Control of NDI processes & changes	1	0.2%	0.2%	1%
92	9Q1	Operator qualification	1	0.2%	0.2%	1%
93	10C1	Delegation of major inspection authority	1	0.2%	0.2%	1%
94	6Q2	Training in sampling techniques	1	0.2%	0.2%	1%
94	7Q10	Control of NDI Equipment	1	0.2%	0.2%	1%
95	6Q1	Statistical sampling inspection plans	1	0.2%	0.2%	0.5%
96	2E5	Changes to Instructions for Continued Airworthiness	1	0.2%	0.2%	0.4%
97	5E1	All special processes in use identified	1	0.2%	0.2%	0.4%
98	7Q8	Use of personal gauges	1	0.2%	0.2%	0.3%
99	14S2	Record of service difficulties	1	0.2%	0.2%	0.3%
100	7Q18	Action on product measured by SOT gauge	1	0.2%	0.2%	0.3%
101	14S1	Feedback on service problems	1	0.2%	0.2%	0.3%
102	4P7	Identification/control of partially accepted parts	1	0.2%	0.2%	0.3%
103	7Q19	Tool & gauge rework/reinspection	1	0.2%	0.2%	0.3%
104	2P1	Manufacturing review of design/technical data changes	1	0.2%	0.2%	0.3%
105	11E1	Engineering review for major/minor changes	1	0.2%	0.2%	0.3%
106	12P1	Manufacturing review of handling specifications, etc.	1	0.2%	0.2%	0.3%
107	10Q9	Verification of shelf-life materials	1	0.2%	0.2%	0.3%
108	4Q2	Location of inspection stations	1	0.2%	0.2%	0.2%
109	2E8	Major/minor design changes	1	0.2%	0.2%	0.2%

TABLE C- 1.—Systemic findings and observations—Continued

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Total Systemic Findings and Observations	Percent of Facilities	Percent of Applicable Facilities with Issues
109	4Q6	Cleaners, solvents, etc., identified	1	0.2%	0.2%	0.2%
110	4Q8	Traceable components identified	1	0.2%	0.2%	0.2%
111	1M2	Organizations described	1	0.2%	0.2%	0.2%
112	12Q7	Control of product removal/issuance	1	0.2%	0.2%	0.2%
113	1M1	Overall policy document	1	0.2%	0.2%	0.2%
114	1M6	Policies/procedures availability	1	0.2%	0.2%	0.2%
115	1Q2	Quality Assurance Manager identified	1	0.2%	0.2%	0.2%
116	7Q7	Accuracy of inspection & test equipment	1	0.2%	0.2%	0.2%
117	1Q1	Quality organizations described	1	0.2%	0.2%	0.2%
118	7P1	Appropriate measuring devices used	1	0.2%	0.2%	0.2%
TOTAL			639			

TABLE C- 2.—Isolated observations

Rank	Criteria	Description	Number of Isolated Observations	Percent of Total Isolated Observations	Percent of Facilities	Percent of Applicable Facilities with Issues
1	7Q1	Approval/inspection of tools & gauges	9	5%	2%	2%
2	2E2	Drawing control system	8	5%	1%	2%
3	12Q5	Identification of age control products	7	4%	1%	2%
4	11Q2	Permanent identification of scrap material	7	4%	1%	1%
5	2E7	Design/Technical data document control	6	3%	1%	1%
6	7Q14	Identification of gauges	6	3%	1%	1%
7	5Q2	Required qualifications/approvals	5	3%	1%	2%
8	5Q3	Accord with process specifications	5	3%	1%	2%
9	11Q1	Control of nonconforming products	5	3%	1%	1%
10	4Q1	Inspection methods and plans	5	3%	1%	1%
11	9Q3	NDI procedures/specifications available & used	4	2%	1%	3%
12	15M1	Internal auditing program	4	2%	1%	1%
13	4P4	Work instructions control manufacturing processes	4	2%	1%	1%
14	10Q2	Use of approved suppliers	4	2%	1%	1%
15	10Q10	Receiving inspection	4	2%	1%	1%
16	4P9	Completed product/part identification	4	2%	1%	1%
17	4Q12	Completion of all inspections & tests	4	2%	1%	1%
18	2C4	Data submittal for TSO minor changes	3	2%	1%	2%
19	5E1	All special processes in use identified	3	2%	1%	1%
20	8E1	Test procedures/instructions established	3	2%	1%	1%
21	10Q1	Initial & periodic evaluations of suppliers	3	2%	1%	1%
22	10Q5	Flow down of technical & quality requirements	3	2%	1%	1%
23	10Q8	Verification of raw material	3	2%	1%	1%
24	1Q5	Tags, forms, etc., described	3	2%	1%	1%
25	12Q3	Storage of conforming parts	3	2%	1%	1%

TABLE C- 2.—Isolated observations—Continued

Rank	Criteria	Description	Number of Isolated Observations	Percent of Total Isolated Observations	Percent of Facilities	Percent of Applicable Facilities with Issues
26	17Q5	Record of completed work	2	1%	0.4%	3%
27	14C3	Submittal of quality system data changes	2	1%	0.4%	1%
28	8E2	Control of test procedure/instruction changes	2	1%	0.4%	1%
29	15M2	Feedback to higher-level management	2	1%	0.4%	1%
30	7Q2	Instructions for acceptance tooling	2	1%	0.4%	0.5%
31	2E8	Major/minor design changes	2	1%	0.4%	0.5%
32	7Q6	Calibration & use in acceptable environment	2	1%	0.4%	0.4%
33	2E1	Design change approval	2	1%	0.4%	0.4%
34	12Q1	Prevention of part damage/contamination	2	1%	0.4%	0.4%
35	7Q12	Calibration records	2	1%	0.4%	0.4%
36	4P6	Familiarity with specifications	2	1%	0.4%	0.4%
37	13Q1	Log books	1	1%	0.2%	4%
38	3AE3	Software problem reporting	1	1%	0.2%	3%
39	9Q12	Critical ultrasonic parameters identified	1	1%	0.2%	3%
40	3AE1	Software Configuration Management Plan	1	1%	0.2%	3%
41	3AE5	Software security	1	1%	0.2%	2%
42	10C3	Direct shipment	1	1%	0.2%	1%
43	9Q14	Critical penetrant parameters identified	1	1%	0.2%	1%
44	6Q8	Criteria for SPC out of control	1	1%	0.2%	1%
45	6Q6	Training in SPC techniques	1	1%	0.2%	1%
46	6Q1	Statistical sampling inspection plans	1	1%	0.2%	0.5%
47	14S5	Approval of service bulletins	1	1%	0.2%	0.5%
48	5Q5	Action on process out of control	1	1%	0.2%	0.4%
49	5Q1	Equipment available & calibrated	1	1%	0.2%	0.4%
50	7Q9	Control of special processing equipment	1	1%	0.2%	0.3%
51	4Q7	Control of environmental conditions	1	1%	0.2%	0.3%
52	7Q19	Tool & gauge rework/reinspection	1	1%	0.2%	0.3%
53	2C2	Major design change approval	1	1%	0.2%	0.3%
54	2C1	Minor design change approval	1	1%	0.2%	0.3%

TABLE C- 2.—Isolated observations—Continued

Rank	Criteria	Description	Number of Isolated Observations	Percent of Total Isolated Observations	Percent of Facilities	Percent of Applicable Facilities with Issues
55	10Q7	Action on problem notification	1	1%	0.2%	0.3%
56	11Q3	MRB established and operational	1	1%	0.2%	0.2%
57	10Q6	Quality Assurance review of purchase documents	1	1%	0.2%	0.2%
58	11Q6	Corrective action required	1	1%	0.2%	0.2%
59	4Q6	Cleaners, solvents, etc., identified	1	1%	0.2%	0.2%
60	4P5	Work instruction revision approval	1	1%	0.2%	0.2%
61	1M5	Policy document review	1	1%	0.2%	0.2%
61	11Q4	Material review record generated	1	1%	0.2%	0.2%
62	7Q16	Inaccurate tools & gauges identified	1	1%	0.2%	0.2%
63	2E3	Technical data change approval	1	1%	0.2%	0.2%
64	4Q8	Traceable components identified	1	1%	0.2%	0.2%
65	4Q3	Issuance of inspection stamps	1	1%	0.2%	0.2%
66	12Q7	Control of product removal/issuance	1	1%	0.2%	0.2%
67	1M1	Overall policy document	1	1%	0.2%	0.2%
68	4P3	Work instructions reflect tech data	1	1%	0.2%	0.2%
69	4P2	Work instructions prepared	1	1%	0.2%	0.2%
70	2E9	Technical data file	1	1%	0.2%	0.2%
71	1M6	Policies/procedures availability	1	1%	0.2%	0.2%
72	2E6	Storage of design documents	1	1%	0.2%	0.2%
73	4Q5	Inspection records	1	1%	0.2%	0.2%
74	1Q4	Quality Manual	1	1%	0.2%	0.2%
TOTAL			176			

TABLE C- 3.—FAR-based observations

Rank	Criteria	Description	Number of FAR-based Observations	Percent of Total FAR-based Observations	Percent of Facilities	Percent of Applicable Facilities with Issues
1	4P9	Completed product/part identification	6	12%	1%	1%
2	4Q2	Location of inspection stations	5	10%	1%	1%
3	1Q6	Record retention schedule	3	6%	1%	1%
4	1Q4	Quality Manual	3	6%	1%	1%
5	5Q3	Accord with process specifications	2	4%	0.4%	1%
6	8E1	Test procedures/instructions established	2	4%	0.4%	1%
7	2E8	Major/minor design changes	2	4%	0.4%	0.5%
8	4P4	Work instructions control manufacturing processes	2	4%	0.4%	0.4%
9	17Q1	Inspection/maintenance program	1	2%	0.2%	1%
10	2C4	Data submittal for TSO minor changes	1	2%	0.2%	1%
11	16Q4	Airworthiness approval tags obtained	1	2%	0.2%	1%
12	6Q1	Statistical sampling inspection plans	1	2%	0.2%	0.5%
13	2E4	AD incorporation into design	1	2%	0.2%	0.4%
14	5E1	All special processes in use identified	1	2%	0.2%	0.4%
15	10E1	Control of supplier design and changes	1	2%	0.2%	0.3%
16	4E2	New/changed process test substantiation	1	2%	0.2%	0.3%
17	14C1	Failure reporting	1	2%	0.2%	0.3%
18	2C2	Major design change approval	1	2%	0.2%	0.3%
19	2C1	Minor design change approval	1	2%	0.2%	0.3%
20	12Q5	Identification of age control products	1	2%	0.2%	0.2%
21	11Q3	MRB established and operational	1	2%	0.2%	0.2%
22	2Q1	QA review of design/technical data changes	1	2%	0.2%	0.2%
23	4P5	Work instruction revision approval	1	2%	0.2%	0.2%
24	10Q5	Flow down of technical & quality requirements	1	2%	0.2%	0.2%
25	2E3	Technical data change approval	1	2%	0.2%	0.2%
26	10Q8	Verification of raw material	1	2%	0.2%	0.2%

TABLE C- 3.— FAR-based observations —Continued

Rank	Criteria	Description	Number of FAR-based Observations	Percent of Total FAR-based Observations	Percent of Facilities	Percent of Applicable Facilities with Issues
27	4P3	Work instructions reflect tech data	1	2%	0.2%	0.2%
28	2E9	Technical data file	1	2%	0.2%	0.2%
29	2E2	Drawing control system	1	2%	0.2%	0.2%
30	7Q4	Traceability to national/international standards	1	2%	0.2%	0.2%
31	11Q1	Control of nonconforming products	1	2%	0.2%	0.2%
32	1Q5	Tags, forms, etc., described	1	2%	0.2%	0.2%
TOTAL			49			

TABLE C- 4.—Systemic findings and observations—APIS holders only

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Systemic Findings and Observations for APIS Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
1	2E3	Technical data change approval	1	14%	100%	100%
1	4P9	Completed product/part identification	1	14%	100%	100%
1	4Q1	Inspection methods and plans	1	14%	100%	100%
1	4Q12	Completion of all inspections & tests	1	14%	100%	100%
1	10Q12	Records of receiving inspection	1	14%	100%	100%
1	12Q3	Storage of conforming parts	1	14%	100%	100%
1	12Q8	Conforming products packaged & shipped	1	14%	100%	100%
TOTAL			7			

TABLE C- 5.—Systemic findings and observations—PC holders only

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Systemic Findings and Observations for PC Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
1	10Q10	Receiving inspection	5	4%	11%	14%
2	4Q12	Completion of all inspections & tests	5	4%	11%	12%
3	10Q5	Flow down of technical & quality requirements	4	3%	9%	12%
4	5Q3	Accord with process specifications	4	3%	9%	11%
5	11Q1	Control of nonconforming products	4	3%	9%	10%
6	4P3	Work instructions reflect tech data	4	3%	9%	10%
7	12Q5	Identification of age control products	4	3%	9%	10%
8	14C3	Submittal of quality system data changes	3	2%	7%	8%
8	15M1	Internal auditing program	3	2%	7%	8%
9	4P4	Work instructions control manufacturing processes	3	2%	7%	8%
10	1Q4	Quality Manual	3	2%	7%	7%
10	2E2	Drawing control system	3	2%	7%	7%
11	4Q5	Inspection records	3	2%	7%	7%
12	9Q9	Records of compliance	2	2%	5%	6%
13	5Q1	Equipment available & calibrated	2	2%	5%	6%
13	5Q4	Records maintained	2	2%	5%	6%
14	4E2	New/changed process test substantiation	2	2%	5%	5%
14	8E2	Control of test procedure/instruction changes	2	2%	5%	5%
14	11Q2	Permanent identification of scrap material	2	2%	5%	5%
14	12Q2	Special environmental controls	2	2%	5%	5%
15	7Q3	Tool & gauge recall system	2	2%	5%	5%
15	8E1	Test procedures/instructions established	2	2%	5%	5%
15	12Q3	Storage of conforming parts	2	2%	5%	5%
16	2E1	Design change approval	2	2%	5%	5%
16	12Q1	Prevention of part damage/contamination	2	2%	5%	5%
17	1Q5	Tags, forms, etc., described	2	2%	5%	5%
17	4P2	Work instructions prepared	2	2%	5%	5%

TABLE C- 5.—Systemic findings and observations—PC holders only —Continued

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Systemic Findings and Observations for PC Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
17	4P9	Completed product/part identification	2	2%	5%	5%
17	4Q1	Inspection methods and plans	2	2%	5%	5%
17	7Q1	Approval/inspection of tools & gauges	2	2%	5%	5%
17	7Q4	Traceability to national/international standards	2	2%	5%	5%
18	7Q12	Calibration records	2	2%	5%	5%
19	3AE5	Software security	1	1%	2%	17%
20	14C4	Relocation of manufacturing facility	1	1%	2%	5%
21	9Q15	Critical eddy current parameters identified	1	1%	2%	5%
21	10Q3	Approval of supplier quality manual	1	1%	2%	5%
22	13Q2	Airworthiness certificates/special flight permits	1	1%	2%	4%
23	9Q1	Operator qualification	1	1%	2%	3%
23	10E1	Control of supplier design and changes	1	1%	2%	3%
23	14S1	Feedback on service problems	1	1%	2%	3%
24	5E1	All special processes in use identified	1	1%	2%	3%
24	7Q10	Control of NDI Equipment	1	1%	2%	3%
24	9Q3	NDI procedures/specifications available & used	1	1%	2%	3%
24	14S2	Record of service difficulties	1	1%	2%	3%
25	2C1	Minor design change approval	1	1%	2%	3%
25	2E8	Major/minor design changes	1	1%	2%	3%
25	10Q9	Verification of shelf-life materials	1	1%	2%	3%
25	11Q7	Corrective action monitored	1	1%	2%	3%
26	7Q18	Action on product measured by SOT gauge	1	1%	2%	3%
26	8Q3	Records of completed tests	1	1%	2%	3%
27	5Q2	Required qualifications/approvals	1	1%	2%	3%
28	7Q13	Adjustment of calibration intervals	1	1%	2%	3%
28	7Q6	Calibration & use in acceptable environment	1	1%	2%	3%
29	11Q4	Material review record generated	1	1%	2%	3%

TABLE C- 5.—Systemic findings and observations—PC holders only —Continued

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Systemic Findings and Observations for PC Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
30	4P5	Work instruction revision approval	1	1%	2%	3%
30	4Q9	Traceability to raw material	1	1%	2%	3%
30	12Q7	Control of product removal/issuance	1	1%	2%	3%
31	2E6	Storage of design documents	1	1%	2%	3%
31	4P1	Change approval	1	1%	2%	3%
31	4Q2	Location of inspection stations	1	1%	2%	3%
31	7Q16	Inaccurate tools & gauges identified	1	1%	2%	3%
32	1M6	Policies/procedures availability	1	1%	2%	2%
32	1Q6	Record retention schedule	1	1%	2%	2%
32	7Q7	Accuracy of inspection & test equipment	1	1%	2%	2%
33	2E7	Design/Technical data document control	1	1%	2%	2%
33	4M1	Operation within production limitations	1	1%	2%	2%
33	4P6	Familiarity with specifications	1	1%	2%	2%
TOTAL			121			

TABLE C- 6.—Systemic findings and observations—PMA holders only

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Systemic Findings and Observations For PMA Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
1	10Q1	Initial & periodic evaluations of suppliers	21	7%	7%	9%
2	4P9	Completed product/part identification	21	7%	7%	8%
3	15M1	Internal auditing program	12	4%	4%	6%
4	4Q1	Inspection methods and plans	11	4%	4%	4%
5	10Q5	Flow down of technical & quality requirements	10	3%	3%	4%
6	10Q8	Verification of raw material	10	3%	3%	4%
7	2C1	Minor design change approval	9	3%	3%	4%
8	7Q1	Approval/inspection of tools & gauges	9	3%	3%	3%
9	12Q5	Identification of age control products	8	3%	3%	4%
10	11Q2	Permanent identification of scrap material	8	3%	3%	3%
11	2E7	Design/Technical data document control	7	2%	2%	3%
12	11Q1	Control of nonconforming products	7	2%	2%	3%
13	2E2	Drawing control system	7	2%	2%	3%
13	4M1	Operation within production limitations	7	2%	2%	3%
14	4Q5	Inspection records	7	2%	2%	3%
15	5Q3	Accord with process specifications	6	2%	2%	4%
16	7Q3	Tool & gauge recall system	6	2%	2%	2%
17	7Q16	Inaccurate tools & gauges identified	5	2%	2%	2%
18	4Q3	Issuance of inspection stamps	5	2%	2%	2%
19	10Q2	Use of approved suppliers	5	2%	2%	2%
20	4Q12	Completion of all inspections & tests	5	2%	2%	2%
21	10Q10	Receiving inspection	5	2%	2%	2%
22	4P4	Work instructions control manufacturing processes	4	1%	1%	2%
23	4P3	Work instructions reflect tech data	4	1%	1%	2%
24	5Q2	Required qualifications/approvals	3	1%	1%	2%
25	5Q4	Records maintained	3	1%	1%	2%

TABLE C- 6.—Systemic findings and observations—PMA holders only —Continued

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Systemic Findings and Observations For PMA Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
26	7Q11	Control of production tooling	3	1%	1%	2%
27	11Q3	MRB established and operational	3	1%	1%	1%
28	11Q4	Material review record generated	3	1%	1%	1%
29	1Q5	Tags, forms, etc., described	3	1%	1%	1%
30	4E1	Accord with FAA-approved design data	3	1%	1%	1%
31	12Q3	Storage of conforming parts	3	1%	1%	1%
32	2E6	Storage of design documents	3	1%	1%	1%
33	4P8	Traceability for split lots	2	1%	1%	1%
34	15M2	Feedback to higher-level management	2	1%	1%	1%
35	14C3	Submittal of quality system data changes	2	1%	1%	1%
36	14C4	Relocation of manufacturing facility	2	1%	1%	1%
37	14C1	Failure reporting	2	1%	1%	1%
38	4P5	Work instruction revision approval	2	1%	1%	1%
39	11Q6	Corrective action required	2	1%	1%	1%
40	7Q6	Calibration & use in acceptable environment	2	1%	1%	1%
41	7Q14	Identification of gauges	2	1%	1%	1%
42	12Q1	Prevention of part damage/contamination	2	1%	1%	1%
42	12Q8	Conforming products packaged & shipped	2	1%	1%	1%
43	10Q12	Records of receiving inspection	2	1%	1%	1%
44	8C3	Approval of test cell correlation/calibration standard	1	0.3%	0.3%	7%
45	16Q2	Control of parts from associated facilities	1	0.3%	0.3%	6%
46	17Q5	Record of completed work	1	0.3%	0.3%	4%
46	17Q6	Completion of all requirements	1	0.3%	0.3%	4%
47	17Q4	Mechanics/repairmen directly in charge	1	0.3%	0.3%	4%
48	3BQ1	Verification prior to use	1	0.3%	0.3%	3%
49	9Q14	Critical penetrant parameters identified	1	0.3%	0.3%	2%
50	9E2	Control of NDI processes & changes	1	0.3%	0.3%	2%
51	6Q10	Corrective action	1	0.3%	0.3%	2%

TABLE C- 6.—Systemic findings and observations—PMA holders only —Continued

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Systemic Findings and Observations For PMA Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
51	9Q3	NDI procedures/specifications available & used	1	0.3%	0.3%	2%
52	6Q1	Statistical sampling inspection plans	1	0.3%	0.3%	1%
53	10Q3	Approval of supplier quality manual	1	0.3%	0.3%	1%
54	2E5	Changes to Instructions for Continued Airworthiness	1	0.3%	0.3%	1%
55	7Q8	Use of personal gauges	1	0.3%	0.3%	1%
56	8E1	Test procedures/instructions established	1	0.3%	0.3%	1%
57	10E1	Control of supplier design and changes	1	0.3%	0.3%	1%
58	1P3	Manufacturing staff qualifications	1	0.3%	0.3%	1%
59	4E2	New/changed process test substantiation	1	0.3%	0.3%	1%
60	12P1	Manufacturing review of handling specifications, etc.	1	0.3%	0.3%	1%
61	11E1	Engineering review for major/minor changes	1	0.3%	0.3%	0.5%
62	11Q7	Corrective action monitored	1	0.3%	0.3%	0.5%
63	7Q13	Adjustment of calibration intervals	1	0.3%	0.3%	0.5%
64	4Q6	Cleaners, solvents, etc., identified	1	0.3%	0.3%	0.5%
65	7Q2	Instructions for acceptance tooling	1	0.3%	0.3%	0.4%
66	10Q6	Quality Assurance review of purchase documents	1	0.3%	0.3%	0.4%
67	4Q8	Traceable components identified	1	0.3%	0.3%	0.4%
68	4P2	Work instructions prepared	1	0.3%	0.3%	0.4%
69	1M1	Overall policy document	1	0.3%	0.3%	0.4%
70	2E3	Technical data change approval	1	0.3%	0.3%	0.4%
71	1Q1	Quality organizations described	1	0.3%	0.3%	0.4%
71	4Q9	Traceability to raw material	1	0.3%	0.3%	0.4%
72	2E1	Design change approval	1	0.3%	0.3%	0.4%
73	2E9	Technical data file	1	0.3%	0.3%	0.4%
73	4Q10	Inspection marking	1	0.3%	0.3%	0.4%
74	4P6	Familiarity with specifications	1	0.3%	0.3%	0.4%
75	7P1	Appropriate measuring devices used	1	0.3%	0.3%	0.4%

TABLE C- 6.—Systemic findings and observations—PMA holders only —Continued

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Systemic Findings and Observations For PMA Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
76	7Q12	Calibration records	1	0.3%	0.3%	0.4%
77	1Q6	Record retention schedule	1	0.3%	0.3%	0.4%
78	12Q4	Segregation of product in storage	1	0.3%	0.3%	0.4%
TOTAL			289			

TABLE C- 7.—Systemic findings and observations—priority parts suppliers only

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Systemic Findings and Observations for Suppliers	Percent of Facilities	Percent of Applicable Facilities with Issues
1	11Q2	Permanent identification of scrap material	4	7%	5%	6%
2	7Q1	Approval/inspection of tools & gauges	4	7%	5%	5%
3	10Q1	Initial & periodic evaluations of suppliers	3	5%	4%	6%
4	10Q5	Flow down of technical & quality requirements	3	5%	4%	5%
5	12Q5	Identification of age control products	3	5%	4%	5%
6	15M1	Internal auditing program	3	5%	4%	5%
7	4P4	Work instructions control manufacturing processes	3	5%	4%	4%
8	9Q14	Critical penetrant parameters identified	2	4%	3%	7%
9	9Q4	Tanks & solutions checked	2	4%	3%	6%
10	2E7	Design/Technical data document control	2	4%	3%	4%
11	11Q4	Material review record generated	2	4%	3%	3%
12	2E2	Drawing control system	2	4%	3%	3%
13	11Q1	Control of nonconforming products	2	4%	3%	3%
14	4Q5	Inspection records	2	4%	3%	3%
15	6Q2	Training in sampling techniques	1	2%	1%	3%
16	5Q3	Accord with process specifications	1	2%	1%	2%
17	8E1	Test procedures/instructions established	1	2%	1%	2%
17	12Q2	Special environmental controls	1	2%	1%	2%
18	4P1	Change approval	1	2%	1%	2%
19	1P3	Manufacturing staff qualifications	1	2%	1%	2%
20	7Q11	Control of production tooling	1	2%	1%	2%
21	7Q19	Tool & gauge rework/reinspection	1	2%	1%	2%
22	1Q3	Quality Assurance staff qualifications	1	2%	1%	2%
23	10Q2	Use of approved suppliers	1	2%	1%	1%
24	4P9	Completed product/part identification	1	2%	1%	1%
24	7Q3	Tool & gauge recall system	1	2%	1%	1%

TABLE C- 7.— Systemic findings and observations—priority parts suppliers only—Continued

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Systemic Findings and Observations for PC Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
25	4P2	Work instructions prepared	1	2%	1%	1%
25	12Q8	Conforming products packaged & shipped	1	2%	1%	1%
26	4P3	Work instructions reflect tech data	1	2%	1%	1%
26	4Q1	Inspection methods and plans	1	2%	1%	1%
27	4Q12	Completion of all inspections & tests	1	2%	1%	1%
27	7Q14	Identification of gauges	1	2%	1%	1%
TOTAL			55			

TABLE C- 8.—Systemic findings and observations—TSO authorization holders only

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Systemic Findings and Observations for TSOA Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
1	12Q5	Identification of age control products	12	7%	9%	12%
2	15M1	Internal auditing program	11	7%	8%	13%
3	10Q1	Initial & periodic evaluations of suppliers	10	6%	8%	9%
4	4P4	Work instructions control manufacturing processes	8	5%	6%	7%
5	4P9	Completed product/part identification	8	5%	6%	6%
6	5Q3	Accord with process specifications	6	4%	5%	10%
7	2C4	Data submittal for TSO minor changes	6	4%	5%	5%
8	10Q2	Use of approved suppliers	5	3%	4%	4%
8	11Q1	Control of nonconforming products	5	3%	4%	4%
9	4Q5	Inspection records	5	3%	4%	4%
10	8E1	Test procedures/instructions established	4	2%	3%	4%
11	10Q8	Verification of raw material	4	2%	3%	4%
12	10Q10	Receiving inspection	4	2%	3%	3%
13	7Q2	Instructions for acceptance tooling	3	2%	2%	3%
14	11Q2	Permanent identification of scrap material	3	2%	2%	3%
15	10Q5	Flow down of technical & quality requirements	3	2%	2%	3%
16	4P2	Work instructions prepared	3	2%	2%	3%
17	2E1	Design change approval	3	2%	2%	2%
18	4Q12	Completion of all inspections & tests	3	2%	2%	2%
19	1Q4	Quality Manual	3	2%	2%	2%
20	16Q3	Export airworthiness approvals obtained	2	1%	2%	4%
21	5Q2	Required qualifications/approvals	2	1%	2%	4%
22	5Q4	Records maintained	2	1%	2%	3%
23	14C3	Submittal of quality system data changes	2	1%	2%	3%
24	11Q6	Corrective action required	2	1%	2%	2%

TABLE C- 8.—Systemic findings and observations—TSO authorization holders only —Continued

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Systemic Findings and Observations for TSOA Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
25	10Q6	Quality Assurance review of purchase documents	2	1%	2%	2%
26	11Q3	MRB established and operational	2	1%	2%	2%
27	7Q3	Tool & gauge recall system	2	1%	2%	2%
28	7Q14	Identification of gauges	2	1%	2%	2%
29	7Q4	Traceability to national/international standards	2	1%	2%	2%
30	12Q3	Storage of conforming parts	2	1%	2%	2%
31	7Q1	Approval/inspection of tools & gauges	2	1%	2%	2%
31	12Q4	Segregation of product in storage	2	1%	2%	2%
32	1Q6	Record retention schedule	2	1%	2%	2%
33	3AE4	Recall/purge of obsolete software	1	1%	1%	4%
34	3BE1	Software Configuration Management Plan	1	1%	1%	4%
35	3AP1	Software identification	1	1%	1%	3%
36	17Q6	Completion of all requirements	1	1%	1%	3%
37	17Q2	Operation within certificate privileges	1	1%	1%	3%
37	17Q3	Work in accordance with Part 43 requirements	1	1%	1%	3%
37	17Q4	Mechanics/repairmen directly in charge	1	1%	1%	3%
38	10C1	Delegation of major inspection authority	1	1%	1%	2%
39	5Q1	Equipment available & calibrated	1	1%	1%	2%
40	10Q3	Approval of supplier quality manual	1	1%	1%	2%
41	8Q3	Records of completed tests	1	1%	1%	2%
42	4P7	Identification/control of partially accepted parts	1	1%	1%	1%
43	11Q7	Corrective action monitored	1	1%	1%	1%
44	1Q3	Quality Assurance staff qualifications	1	1%	1%	1%
45	2P1	Manufacturing review of design/technical data changes	1	1%	1%	1%

TABLE C- 8.—Systemic findings and observations—TSO authorization holders only —Continued

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Systemic Findings and Observations for TSOA Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
46	11Q4	Material review record generated	1	1%	1%	1%
47	7Q6	Calibration & use in acceptable environment	1	1%	1%	1%
47	14C1	Failure reporting	1	1%	1%	1%
48	4Q3	Issuance of inspection stamps	1	1%	1%	1%
49	4P1	Change approval	1	1%	1%	1%
50	1M2	Organizations described	1	1%	1%	1%
50	4P3	Work instructions reflect tech data	1	1%	1%	1%
51	2E3	Technical data change approval	1	1%	1%	1%
52	2E7	Design/Technical data document control	1	1%	1%	1%
52	4Q1	Inspection methods and plans	1	1%	1%	1%
52	10Q12	Records of receiving inspection	1	1%	1%	1%
53	4E1	Accord with FAA-approved design data	1	1%	1%	1%
53	4Q10	Inspection marking	1	1%	1%	1%
54	1Q2	Quality Assurance Manager identified	1	1%	1%	1%
55	2E9	Technical data file	1	1%	1%	1%
TOTAL			167			

TABLE C- 9.—Isolated observations—APIS holders only

Rank	Criteria	Description	Number of Isolated Observations	Percent of Isolated Observations for APIS Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
TOTAL			0			

No isolated observations were recorded for APIS holders in FY 1998.

TABLE C- 10.—Isolated observations—PC holders only

Rank	Criteria	Description	Number of Isolated Observations	Percent of Isolated Observations for PC Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
1	11Q2	Permanent identification of scrap material	4	9%	9%	11%
2	7Q14	Identification of gauges	4	9%	9%	10%
3	4P4	Work instructions control manufacturing processes	3	7%	7%	8%
4	2E2	Drawing control system	3	7%	7%	7%
5	15M1	Internal auditing program	2	4%	5%	5%
6	11Q1	Control of nonconforming products	2	4%	5%	5%
7	12Q5	Identification of age control products	2	4%	5%	5%
8	2E7	Design/Technical data document control	2	4%	5%	5%
9	3AE1	Software Configuration Management Plan	1	2%	2%	14%
10	9Q12	Critical ultrasonic parameters identified	1	2%	2%	5%
11	13Q1	Log books	1	2%	2%	4%
12	9Q3	NDI procedures/specifications available & used	1	2%	2%	3%
13	10Q5	Flow down of technical & quality requirements	1	2%	2%	3%
14	1M5	Policy document review	1	2%	2%	3%
14	15M2	Feedback to higher-level management	1	2%	2%	3%
15	5Q2	Required qualifications/approvals	1	2%	2%	3%
15	10Q1	Initial & periodic evaluations of suppliers	1	2%	2%	3%
16	7Q6	Calibration & use in acceptable environment	1	2%	2%	3%
16	8E2	Control of test procedure/instruction changes	1	2%	2%	3%
17	4Q6	Cleaners, solvents, etc., identified	1	2%	2%	3%
17	11Q4	Material review record generated	1	2%	2%	3%
18	12Q3	Storage of conforming parts	1	2%	2%	3%
19	4P3	Work instructions reflect tech data	1	2%	2%	3%
19	7Q16	Inaccurate tools & gauges identified	1	2%	2%	3%

TABLE C- 10.— Isolated observations—PC holders only —Continued

Rank	Criteria	Description	Number of Isolated Observations	Percent of Isolated Observations for PC Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
19	7Q19	Tool & gauge rework/reinspection	1	2%	2%	3%
19	12Q1	Prevention of part damage/contamination	1	2%	2%	3%
20	1M1	Overall policy document	1	2%	2%	2%
20	1M6	Policies/procedures availability	1	2%	2%	2%
20	1Q5	Tags, forms, etc., described	1	2%	2%	2%
20	7Q1	Approval/inspection of tools & gauges	1	2%	2%	2%
21	4Q12	Completion of all inspections & tests	1	2%	2%	2%
22	4P6	Familiarity with specifications	1	2%	2%	2%
TOTAL			46			

TABLE C- 11.— Isolated observations—PMA holders only

Rank	Criteria	Description	Number of Isolated Observations	Percent of Isolated Observations for PMA Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
1	5Q3	Accord with process specifications	3	8%	1%	3%
2	12Q5	Identification of age control products	3	8%	1%	2%
3	4Q1	Inspection methods and plans	3	8%	1%	3%
4	4P9	Completed product/part identification	3	8%	1%	2%
5	17Q5	Record of completed work	2	5%	1%	2%
6	5Q2	Required qualifications/approvals	2	5%	1%	2%
7	5E1	All special processes in use identified	2	5%	1%	1%
8	10Q8	Verification of raw material	2	5%	1%	1%
9	2E2	Drawing control system	2	5%	1%	1%
10	10Q10	Receiving inspection	2	5%	1%	1%
11	10C3	Direct shipment	1	3%	0%	1%
12	6Q1	Statistical sampling inspection plans	1	3%	0%	1%
13	8E1	Test procedures/instructions established	1	3%	0%	1%
14	4Q8	Traceable components identified	1	3%	0%	1%
15	2C2	Major design change approval	1	3%	0%	1%
16	2C1	Minor design change approval	1	3%	0%	1%
16	4P4	Work instructions control manufacturing processes	1	3%	0%	1%
17	10Q5	Flow down of technical & quality requirements	1	3%	0%	1%
18	2E3	Technical data change approval	1	3%	0%	1%
19	10Q2	Use of approved suppliers	1	3%	0%	1%
20	11Q1	Control of nonconforming products	1	3%	0%	1%
21	12Q1	Prevention of part damage/contamination	1	3%	0%	0.5%
22	4Q12	Completion of all inspections & tests	1	3%	0%	0.5%
23	7Q1	Approval/inspection of tools & gauges	1	3%	0%	0.5%
24	4Q5	Inspection records	1	3%	0%	0.5%
TOTAL			39			

TABLE C- 12.— Isolated observations— priority parts suppliers only

Rank	Criteria	Description	Number of Isolated Observations	Percent of Isolated Observations for Suppliers	Percent of Facilities	Percent of Applicable Facilities with Issues
1	9Q3	NDI procedures/specifications available & used	3	13%	4%	8%
2	7Q1	Approval/inspection of tools & gauges	3	13%	4%	4%
3	10Q2	Use of approved suppliers	2	8%	3%	3%
4	9Q14	Critical penetrant parameters identified	1	4%	1%	4%
5	2E8	Major/minor design changes	1	4%	1%	3%
6	6Q6	Training in SPC techniques	1	4%	1%	3%
7	5Q3	Accord with process specifications	1	4%	1%	2%
8	7Q9	Control of special processing equipment	1	4%	1%	2%
9	4Q7	Control of environmental conditions	1	4%	1%	2%
10	2E7	Design/Technical data document control	1	4%	1%	2%
11	12Q5	Identification of age control products	1	4%	1%	2%
12	7Q2	Instructions for acceptance tooling	1	4%	1%	2%
13	11Q6	Corrective action required	1	4%	1%	2%
14	2E2	Drawing control system	1	4%	1%	2%
15	11Q2	Permanent identification of scrap material	1	4%	1%	1%
16	11Q1	Control of nonconforming products	1	4%	1%	1%
17	7Q12	Calibration records	1	4%	1%	1%
18	4P6	Familiarity with specifications	1	4%	1%	1%
19	7Q14	Identification of gauges	1	4%	1%	1%
TOTAL			24			

TABLE C- 13.— Isolated observations—TSO authorization holders only

Rank	Criteria	Description	Number of Isolated Observations	Percent of Isolated Observations for TSOA Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
1	7Q1	Approval/inspection of tools & gauges	4	6%	3%	3%
2	2C4	Data submittal for TSO minor changes	3	4%	2%	3%
3	2E7	Design/Technical data document control	3	4%	2%	3%
4	5Q2	Required qualifications/approvals	2	3%	2%	4%
5	14C3	Submittal of quality system data changes	2	3%	2%	3%
6	15M1	Internal auditing program	2	3%	2%	2%
7	11Q2	Permanent identification of scrap material	2	3%	2%	2%
8	10Q1	Initial & periodic evaluations of suppliers	2	3%	2%	2%
9	8E1	Test procedures/instructions established	2	3%	2%	2%
10	4Q1	Inspection methods and plans	2	3%	2%	2%
11	12Q3	Storage of conforming parts	2	3%	2%	2%
12	2E1	Design change approval	2	3%	2%	2%
12	10Q10	Receiving inspection	2	3%	2%	2%
13	2E2	Drawing control system	2	3%	2%	2%
14	1Q5	Tags, forms, etc., described	2	3%	2%	2%
15	4Q12	Completion of all inspections & tests	2	3%	2%	2%
16	6Q8	Criteria for SPC out of control	1	1%	1%	5%
17	3AE3	Software problem reporting	1	1%	1%	4%
18	3AE5	Software security	1	1%	1%	3%
19	5Q5	Action on process out of control	1	1%	1%	2%
20	5Q1	Equipment available & calibrated	1	1%	1%	2%
21	5Q3	Accord with process specifications	1	1%	1%	2%
22	5E1	All special processes in use identified	1	1%	1%	2%
23	14S5	Approval of service bulletins	1	1%	1%	1%
24	15M2	Feedback to higher-level management	1	1%	1%	1%
25	7Q2	Instructions for acceptance tooling	1	1%	1%	1%
25	10Q7	Action on problem notification	1	1%	1%	1%
26	12Q5	Identification of age control products	1	1%	1%	1%

TABLE C- 13.— Isolated observations –TSO authorization holders only —Continued

Rank	Criteria	Description	Number of Isolated Observations	Percent of Isolated Observations for TSOA Holders	Percent of Facilities	Percent of Applicable Facilities with Issues
27	10Q6	Quality Assurance review of purchase documents	1	1%	1%	1%
28	11Q3	MRB established and operational	1	1%	1%	1%
29	8E2	Control of test procedure/instruction changes	1	1%	1%	1%
30	7Q6	Calibration & use in acceptable environment	1	1%	1%	1%
31	10Q5	Flow down of technical & quality requirements	1	1%	1%	1%
32	4P5	Work instruction revision approval	1	1%	1%	1%
32	4Q3	Issuance of inspection stamps	1	1%	1%	1%
33	10Q8	Verification of raw material	1	1%	1%	1%
33	12Q7	Control of product removal/issuance	1	1%	1%	1%
34	7Q14	Identification of gauges	1	1%	1%	1%
35	4P2	Work instructions prepared	1	1%	1%	1%
35	10Q2	Use of approved suppliers	1	1%	1%	1%
35	11Q1	Control of nonconforming products	1	1%	1%	1%
36	2E8	Major/minor design changes	1	1%	1%	1%
37	7Q12	Calibration records	1	1%	1%	1%
38	2E9	Technical data file	1	1%	1%	1%
38	4P9	Completed product/part identification	1	1%	1%	1%
39	2E6	Storage of design documents	1	1%	1%	1%
40	1Q4	Quality Manual	1	1%	1%	1%
TOTAL			67			

TABLE C- 14.— Systemic findings and observations –international facilities

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Total Systemic Findings and Observations	Percent of Facilities	Percent of Applicable Facilities with Issues
1	2E7	Design/Technical data document control	6	8%	30%	30%
2	5Q3	Accord with process specifications	4	5%	20%	24%
3	7Q11	Control of production tooling	3	4%	15%	18%
4	10Q1	Initial & periodic evaluations of suppliers	3	4%	15%	19%
5	11Q6	Corrective action required	3	4%	15%	17%
6	1M6	Policies/procedures availability	2	3%	10%	11%
7	4P1	Change approval	2	3%	10%	10%
8	4P4	Work instructions control manufacturing processes	2	3%	10%	10%
9	4P7	Identification/control of partially accepted parts	2	3%	10%	14%
10	5Q4	Records maintained	2	3%	10%	12%
11	11Q7	Corrective action monitored	2	3%	10%	11%
12	12Q1	Prevention of part damage/contamination	2	3%	10%	11%
12	12Q3	Storage of conforming parts	2	3%	10%	11%
13	15M1	Internal auditing program	2	3%	10%	10%
14	1M5	Policy document review	1	1%	5%	6%
15	2E1	Design change approval	1	1%	5%	6%
16	2E2	Drawing control system	1	1%	5%	5%
17	2E3	Technical data change approval	1	1%	5%	6%
17	2E9	Technical data file	1	1%	5%	5%
18	2P1	Manufacturing review of design/technical data changes	1	1%	5%	9%
19	4E2	New/changed process test substantiation	1	1%	5%	6%
20	4P2	Work instructions prepared	1	1%	5%	5%
21	4P5	Work instruction revision approval	1	1%	5%	5%
22	4P6	Familiarity with specifications	1	1%	5%	5%
23	4Q1	Inspection methods and plans	1	1%	5%	5%
24	4Q12	Completion of all inspections & tests	1	1%	5%	5%
25	4Q5	Inspection records	1	1%	5%	5%
26	4Q9	Traceability to raw material	1	1%	5%	5%
26	5E1	All special processes in use identified	1	1%	2%	3%

TABLE C- 14.— Systemic findings and observations –international facilities —Continued

Rank	Criteria	Description	Number of Systemic Findings and Observations	Percent of Total Systemic Findings and Observations	Percent of Facilities	Percent of Applicable Facilities with Issues
27	2E7	Design/Technical data document control	1	1%	2%	3%
27	2E9	Technical data file	1	1%	2%	3%
27	5Q1	Equipment available & calibrated	1	1%	2%	3%
27	11Q2	Permanent identification of scrap material	1	1%	2%	3%
27	11Q1	Control of nonconforming products	1	1%	2%	3%
28	10Q10	Receiving inspection	1	1%	2%	2%
28	10Q8	Verification of raw material	1	1%	2%	2%
29	4P2	Work instructions prepared	1	1%	2%	2%
29	7Q14	Identification of gauges	1	1%	2%	2%
30	4P6	Familiarity with specifications	1	1%	2%	2%
30	4P9	Completed product/part identification	1	1%	2%	2%
30	4Q12	Completion of all inspections & tests	1	1%	2%	2%
30	12Q3	Storage of conforming parts	1	1%	2%	2%
TOTAL			67			

TABLE C- 15.—Isolated observations –international facilities

Rank	Criteria	Description	Number of Isolated Observations	Percent of Isolated Observations	Percent of Facilities	Percent of Applicable Facilities with Issues
1	4P4	Work instructions control manufacturing processes	3	7%	7%	7%
2	4P3	Work instructions reflect tech data	3	7%	7%	7%
3	9Q14	Critical penetrant parameters identified	2	5%	5%	8%
4	7Q16	Inaccurate tools & gauges identified	2	5%	5%	6%
5	2E7	Design/Technical data document control	2	5%	5%	5%
5	5Q1	Equipment available & calibrated	2	5%	5%	5%
5	7Q12	Calibration records	2	5%	5%	5%
5	10Q12	Records of receiving inspection	2	5%	5%	5%
6	4Q5	Inspection records	2	5%	5%	5%
6	12Q3	Storage of conforming parts	2	5%	5%	5%
7	8E2	Control of test procedure/instruction changes	1	2%	2%	3%
8	9E2	Control of NDI processes & changes	1	2%	2%	3%
9	4Q2	Location of inspection stations	1	2%	2%	3%
10	11Q3	MRB established and operational	1	2%	2%	3%
11	5E2	New/changed process test substantiation	1	2%	2%	3%
11	7Q6	Calibration & use in acceptable environment	1	2%	2%	3%
11	12Q2	Special environmental controls	1	2%	2%	3%
12	1Q4	Quality Manual	1	2%	2%	3%
13	2E1	Design change approval	1	2%	2%	3%
13	7Q15	Care of tools & gauges	1	2%	2%	3%
13	11Q7	Corrective action monitored	1	2%	2%	3%
13	15M2	Feedback to higher-level management	1	2%	2%	3%
14	5E1	All special processes in use identified	1	2%	2%	3%
14	11Q1	Control of nonconforming products	1	2%	2%	3%
14	11Q2	Permanent identification of scrap material	1	2%	2%	3%
15	4P5	Work instruction revision approval	1	2%	2%	2%
15	11Q4	Material review record generated	1	2%	2%	2%
16	2E2	Drawing control system	1	2%	2%	2%
16	4Q9	Traceability to raw material	1	2%	2%	2%

TABLE C- 15.— Isolated observations –international facilities —Continued

TABLE C- 15.— Isolated observations –international facilities —Continued

Rank	Criteria	Description	Number of Isolated Observations	Percent of Isolated Observations	Percent of Facilities	Percent of Applicable Facilities with Issues
16	12Q4	Segregation of product in storage	1	2%	2%	2%
17	12Q1	Prevention of part damage/contamination	1	2%	2%	2%
TOTAL			43			

C2. Delegated Facilities

This section provides the data collected during FY 1998 ACSEP evaluations conducted at DAS, SFAR-36, and DOA facilities. The first two tables (*Table C-16 and C-17*) present data for all delegated facilities combined. The following six tables present data from the individual delegation types. *Tables C-18 through C-20* provide data on systemic issues and *Tables C-21 through C-23* provide data for isolated observations.

TABLE C- 16.—Systemic findings and observations – delegated facilities

Rank	Criteria	Name	Number Of Systemic Findings And Observations	Percent Of All Systemic Findings And Observations	Percent Of All Facilities That Had Systemic Findings And Observations
1	6D2	Conformity inspections documented	4	11%	16%
2	3D5	Technical/repair data is approved	3	8%	12%
3	1D13	List of products repaired or modified	2	5%	8%
3	3D3	Classification of data being approved	2	5%	8%
3	8D1	Submittal of required information to FAA	2	5%	8%
4	6D4	"At-risk" conformity inspection records reviewed	1	3%	4%
5	2D25	Proper completion of STC certificates	1	3%	4%
6	2D20	Approval/control of AFM/AFMS	1	3%	4%
6	7D1	Application for airworthiness certification submitted	1	3%	4%
7	10D1	Internal auditing program	1	3%	4%
7	2D21	TIR/STIR to document conformity, inspection, and tests	1	3%	4%
7	7D2	Limitations and conditions for experimental airworthiness	1	3%	4%
8	2D17	Conformity inspections conducted prior to testing	1	3%	4%
9	2D6	Submittal of Letter of Intent to FAA	1	3%	4%
10	4D1	Control of changes to type design data	1	3%	4%
10	4D3	Minor design change approval method	1	3%	4%
10	4D4	Approval of major changes to type design	1	3%	4%

TABLE C- 16.—Systemic findings and observations – delegated facilities —Continued

Rank	Criteria	Name	Number Of Systemic Findings And Observations	Percent Of All Systemic Findings And Observations	Percent Of All Facilities That Had Systemic Findings And Observations
11	1D18	Tags, forms, etc., described/controlled	1	3%	4%
12	5D7	Results documented and approved	1	3%	4%
12	9D1	Instructions for Continued Airworthiness developed	1	3%	4%
13	5D2	Authorized staff members identified	1	3%	4%
13	9D9	Record of reported service difficulties maintained	1	3%	4%
14	1D12	List of engineer, flight test, and inspection staff	1	3%	4%
15	1D1	Use of FAA-approved Procedure Manual/Handbook	1	3%	4%
15	1D11	Procedures, regulations, and policies are made available	1	3%	4%
15	2D27	Documentation/approval of type design data	1	3%	4%
15	3D1	Control of type design data	1	3%	4%
15	3D2	Use of approved documents and forms	1	3%	4%
15	8D2	Notification of changes to authorization eligibility	1	3%	4%
TOTAL			37		

TABLE C- 17.—Isolated findings and observations – delegated facilities

Rank	Criteria	Name	Number Of Isolated Observations	Percent Of All Isolated Observations	Percent Of All Facilities That Had Isolated Observations
1	2D25	Proper completion of STC certificates	1	7%	4%
2	7D2	Limitations and conditions for experimental airworthiness	1	7%	4%
3	2D17	Conformity inspections conducted prior to testing	1	7%	4%
3	6D6	Control on nonconforming products/parts	1	7%	4%
4	2D26	Certification summary report	1	7%	4%
4	2D6	Submittal of Letter of Intent to FAA	1	7%	4%
5	4D5	Use of approved documents and forms	1	7%	4%
6	1D18	Tags, forms, etc., described/controlled	1	7%	4%
7	5D7	Results documented and approved	1	7%	4%
8	1D15	Qualifications of delegated facility staff	1	7%	4%
9	2D27	Documentation/approval of type design data	1	7%	4%
9	3D2	Use of approved documents and forms	1	7%	4%
9	3D5	Technical/repair data is approved	1	7%	4%
9	8D2	Notification of changes to authorization eligibility	1	7%	4%
TOTAL			14		

TABLE C- 18.—Systemic findings and observations – DAS facilities

Rank	Criteria	Name	Number Of Systemic Findings And Observations	Percent Of All Systemic Findings And Observations for DAS facilities	Percent Of All DAS Facilities That Had Systemic Findings And Observations
1	6D2	Conformity inspections documented	4	15%	29%
2	3D5	Technical/repair data is approved	2	7%	14%
3	6D4	“At-risk” conformity inspection records reviewed	1	4%	7%
4	10D1	Internal auditing program	1	4%	7%
5	2D20	Approval/control of AFM/AFMS	1	4%	7%
5	2D25	Proper completion of STC certificates	1	4%	7%
5	7D1	Application for airworthiness certification submitted	1	4%	7%
5	7D2	Limitations and conditions for experimental airworthiness	1	4%	7%
6	2D21	TIR/STIR to document conformity, inspection, and tests	1	4%	7%
7	1D18	Tags, forms, etc., described/controlled	1	4%	7%
7	2D17	Conformity inspections conducted prior to testing	1	4%	7%
7	4D3	Minor design change approval method	1	4%	7%
7	4D4	Approval of major changes to type design	1	4%	7%
8	1D12	List of engineer, flight test, and inspection staff	1	4%	7%
8	2D27	Documentation/approval of type design data	1	4%	7%
8	2D6	Submittal of Letter of Intent to FAA	1	4%	7%
8	3D1	Control of type design data	1	4%	7%
8	3D3	Classification of data being approved	1	4%	7%
8	5D2	Authorized staff members identified	1	4%	7%
8	5D7	Results documented and approved	1	4%	7%
8	8D1	Submittal of required information to FAA	1	4%	7%
8	8D2	Notification of changes to authorization eligibility	1	4%	7%
8	9D1	Instructions for Continued Airworthiness developed	1	4%	7%
TOTAL			27		

TABLE C- 19.—Systemic findings and observations – SFAR-36 facilities

Rank	Criteria	Name	Number Of Systemic Findings And Observations	Percent Of All Systemic Findings And Observations for SFAR-36 facilities	Percent Of All SFAR-36 Facilities That Had Systemic Findings And Observations
1	1D13	List of products repaired or modified	2	22%	20%
2	4D1	Control of changes to type design data	1	11%	10%
3	9D9	Record of reported service difficulties maintained	1	11%	10%
4	1D1	Use of FAA-approved Procedure Manual/Handbook	1	11%	10%
4	1D11	Procedures, regulations, and policies are made available	1	11%	10%
4	3D2	Use of approved documents and forms	1	11%	10%
4	3D3	Classification of data being approved	1	11%	10%
4	8D1	Submittal of required information to FAA	1	11%	10%
TOTAL			9		

TABLE C- 20.—Systemic findings and observations – DOA facilities

Rank	Criteria	Name	Number Of Systemic Findings And Observations	Percent Of All Systemic Findings And Observations for DOA facilities	Percent Of All DOA Facilities That Had Systemic Findings And Observations
1	3D5	Technical/repair data is approved	1	100%	100%
TOTAL			1		

TABLE C- 21.— Isolated findings and observations – DAS facilities

Rank	Criteria	Name	Number Of Isolated Observations	Percent Of All Isolated Observations for DAS facilities	Percent Of All DAS Facilities That Had Isolated Observations
1	2D25	Proper completion of STC certificates	1	9%	7%
1	7D2	Limitations and conditions for experimental airworthiness	1	9%	7%
1	6D6	Control on nonconforming products/parts	1	9%	7%
2	1D15	Qualifications of delegated facility staff	1	9%	7%
3	1D18	Tags, forms, etc., described/controlled	1	9%	7%
3	2D17	Conformity inspections conducted prior to testing	1	9%	7%
4	2D27	Documentation/approval of type design data	1	9%	7%
4	2D6	Submittal of Letter of Intent to FAA	1	9%	7%
4	5D7	Results documented and approved	1	9%	7%
4	2D26	Certification summary report	1	9%	7%
4	3D2	Use of approved documents and forms	1	9%	7%
TOTAL			11		

TABLE C- 22.— Isolated findings and observations – SFAR-36 facilities

Rank	Criteria	Name	Number Of Isolated Observations	Percent Of All Isolated Observations for SFAR-36 facilities	Percent Of All SFAR-36 Facilities That Had Isolated Observations
1	3D5	Technical/repair data is approved	1	50%	10%
1	8D2	Notification of changes to authorization eligibility	1	50%	10%
TOTAL			2		

TABLE C- 23.— Isolated findings and observations – DOA facilities

Rank	Criteria	Name	Number Of Isolated Observations	Percent Of All Isolated Observations for DOA facilities	Percent Of All DOA Facilities That Had Isolated Observations
1	4D5	Use of approved documents and forms	1	100%	100%
TOTAL			1		

APPENDIX D

CORRELATION BETWEEN FACILITY COMPLEXITY AND THE PROBABILITY OF SYSTEMIC ISSUES

When a direct comparison among facilities types is made, PC holders appear to have a higher percentage of facilities in noncompliance than other facility types. They also have more findings and observations. However, we believe that this direct comparison among the facility types is biased. It is hypothesized that regardless of their facility type, larger facilities with complex systems have a greater chance of having findings and observations than small facilities with simple systems. For example, a 20,000-employee supplier of a complex assembly has a greater chance of having discrepancies than a four-employee supplier – simply due to the differences in their sizes and nature of their systems. There are only a handful of PC holders with a small number of employees and operating under simplistic quality systems. However, numerous priority parts suppliers, PMA holders, and TSO authorization holders are small and operate under simple systems. Therefore, comparing PC holders to suppliers without compensating for their varying size and complexity would be inappropriate. The obvious solution would be to compare facilities of similar size and complexity. A method was investigated to account for these differences and make the necessary adjustments to the analysis in order to make comparisons between the different facility types without this bias.

The number of evaluators, duration of the evaluations, total evaluator hours expended, the size of the facilities, and the type of facilities were all explored as possible measures of facility complexity. Regression analysis showed that the number of evaluators was the most reliable indicator of facility complexity¹⁷. This is because the number of evaluators selected to conduct an ACSEP evaluation is determined prior to the evaluation with careful consideration to: a facility's size, physical layout, number and types of certificates held, number of applicable subsystems, product number and complexity, number of employees associated with these products, the number of procedures controlling these products, and any unique or special circumstances. The number of evaluators would therefore be a very comprehensive indicator of facility complexity.

The duration of evaluations also incorporates the elements just listed, as does the evaluator hours expended performing the evaluations. No correlation exists between evaluation duration and the number or frequency of receiving findings or observations. Only a very weak correlation exists between the number of evaluator hours expended on the evaluation and the frequency or number of issues received. Facility size and facility type consider only one element of complexity each. Therefore, both of these were ruled out as not being comprehensive measures of facility complexity.

¹⁷ The frequency of facilities receiving findings and observations had a logarithmic correlation with a 98 percent coefficient of dependence to the number of evaluators present during the evaluation. The number of findings and observations recorded had a linear correlation with a 98 percent coefficient of dependence to the number of evaluators present during the evaluation.

It should be noted that the number of evaluators is neither a guarantee of findings nor is it in itself the determinant of the probability of a facility having findings recorded. There were several occurrences of large evaluation teams not finding any systemic issues and several occurrences of small evaluation teams finding several systemic issues. This would support the theorem that the number of evaluators is only an indicator of facility complexity. By possessing a greater number of procedures and policies, more complex systems would have a higher probability of being in noncompliance. The probability of noncompliance does not, in itself, relate to the number of evaluators. Conversely, the number of evaluators, in itself, does not relate to the number of noncompliances (weak coefficient of dependence as seen in *figure D-1*). The number of evaluators is a measure of facility complexity; complexity relates to the number of possibilities for noncompliance; the number of possibilities for noncompliance defines the probability for noncompliance; and the probability for noncompliance determines the number of findings.

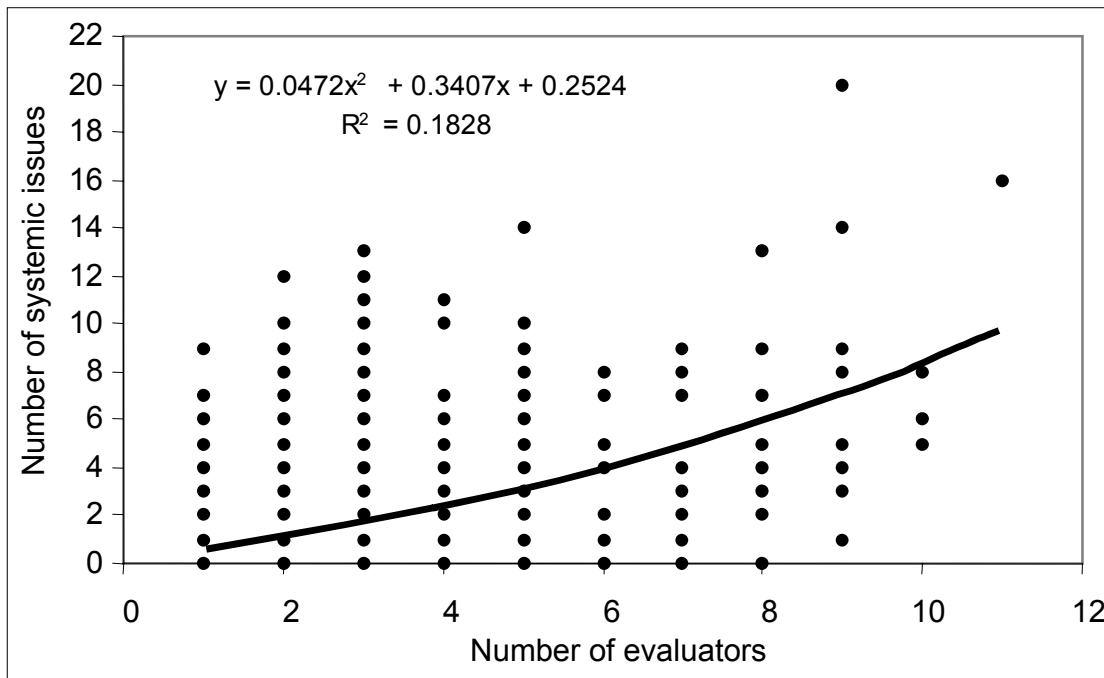


Figure D-1.—Scatter diagram of systemic findings/observations vs. number of evaluators present at ACSEP evaluations.

APPENDIX E

ANALYSIS METHODS AND ASSUMPTIONS

E1. Sample/Inferential Error

One of the purposes of an ACSEP evaluation is to test a facility's compliance with the FAR and its own established policies and procedures. In a very small facility with very few procedures and low production, the test for compliance could be a 100 percent check of all available data. For all other facilities, however, a 100 percent check of all available data would be extremely time consuming, uneconomical, and disruptive to the facility's productivity. For all except the smallest of facilities, ACSEP uses the widely accepted practice of examining only a portion of the available documentation and extrapolating the results to conclusions about the balance of the documentation not reviewed. The examination of a small portion of the available documentation and drawing conclusions about the whole of a facility's documented system is defined as a sampling process.

Any inference to the population based upon this sample has the possibility of slight error. There is no guarantee that the sample of documentation selected during the evaluation will exactly reflect the condition of all of the available documentation; just as there is no guarantee that ten flips of a fair coin will always result in five heads and five tails.

The charts in this report reflect the exact results of the evaluations performed within the time period specified. Statements as to the compliance rate of those particular facilities evaluated can be made directly off the figures and tables. However, using the data from the evaluations analyzed in this report to predict industry trends, as opposed to simply reporting historical results, is subject to the statistical principle of sample error.

Using *figure 3-17* as an example, 20 percent of the domestic facilities evaluated for FY 1998 had systemic manufacturing process issues. In addition, the data can be used to predict, within a 95 percent confidence level, that no less than 17 percent and no more than 23 percent (20 percent \pm 3 percent) of all domestic facilities have systemic compliance issues in manufacturing processes. Please note that the three percent error is only a measure of the reliability of predictions based on the data and is not a measure of the accuracy of the data itself.

E2. Sample/Inferential Error When Reporting the Number of Noncompliances

As stated earlier, time and resources limit the amount of documentation that can be evaluated at any one ACSEP evaluation. The ACSEP team uses judgement to select those documents to evaluate that best represent the total system being evaluated. The use of sampling, good evaluation judgment, and skilled evaluators will produce an evaluation report that statistically reflects compliance issues for a particular facility for a particular period of time. However, these limiting factors also limit the total number of potential

findings and observations reported. Given unlimited time and resources, there theoretically could be an indeterminate number of findings or observations. Lacking a finite number of possible findings or observations, the population size of possible findings or observations is, therefore, assumed to be large. Based on this assumption, the equation used to calculate the prediction error is:

$$PE_{\%} = \pm z \sqrt{\frac{p(1-p)}{n}} \quad (1)$$

where $PE_{\%}$ = prediction error
 z = confidence coefficient factor
 p = percent of facilities with findings and/or observations
 n = sample size (number of finding and/or observations)

Equation (1) proves adequate if the sample size is equal to or greater than 30. Should the sample size be less than 30, or p is either close to zero or one-hundred percent (if the product $pn < 5$ or the product $(1-p)n < 5$), equation (2) is more accurate in determining the limits of the analysis.

$$p_{\lim} = \frac{p + \frac{z^2}{2n} \pm z \sqrt{\frac{p(1-p)}{n} + \frac{z^2}{4n^2}}}{1 + \frac{z^2}{n}} \quad (2)$$

where p_{\lim} = upper and lower confidence limit of the analysis
 z = confidence coefficient factor
 p = percent of facilities with findings and/or observations
 n = sample size (number of finding and/or observations or the number of facilities considered satisfying the condition being tested)

E3. Sample Error When Reporting Facility Frequencies and Other Finite Populations

In those cases when the population is known and it is sampled without replacement, the above equations may overstate the inferential error. This is especially true when the sample size is greater than five percent of the population size. To adjust for this difference, Equation (1) is modified as follows:

$$SE_{\%} = \pm z \sqrt{\frac{p(1-p)}{n}} \sqrt{\frac{N-n}{N-1}} \quad (3)$$

where $SE_{\%}$ = sample error
 z = confidence coefficient factor
 p = percent of facilities with findings and/or observations
 n = sample size (number of finding and/or observations or the number of facilities considered satisfying the condition being tested)
 N = population size

Equation (2) is modified as follows:

$$SE_{\%} = \left(\frac{p + \frac{z^2}{2n} \pm z \sqrt{\frac{p(1-p)}{n} + \frac{z^2}{4n^2}}}{1 + \frac{z^2}{n}} - p \right) \left(\sqrt{\frac{N-n}{N-1}} \right) \quad (4)$$

where $SE_{\%}$ = sample error
 z = confidence coefficient factor
 p = percent of facilities with findings and/or observations
 n = sample size (number of finding and/or observations or the number of facilities considered satisfying the condition being tested)
 N = population size

E4. Pooling of Multi-year Data

The pooling of two fiscal years of data is considered a justifiable method of strengthening the reliability of the analyses since it does not introduce any additional variants into the analysis. Because the shortest time interval between an ACSEP evaluation being repeated at any one facility is two years, pooling of two years of data represents an analysis of only one evaluation from any one facility. Therefore, data from two consecutive years are considered to be from the same total population and pooling the two sets of data in some of the analyses used in this report is considered justified.

In the case of PC holders, the pooling of two fiscal years of data is considered necessary to attain a random sample of facilities for analysis. The compliance levels for PC holders appear to rise and fall in a two-year cycle. This is theorized to be caused by a facility selection bias initiated (see *Section 3.4.2*) in FY 1993 when ACSEP first transitioned from QASAR (see *Appendix A*). In order to counteract the affects of the biannual cycle, data from two consecutive years is used.

E5. Selection of the Confidence Interval

The conclusions reached in this report are based on analyses of a finite set of data (i.e., sample data). Statements made concerning probability distributions of the true population are based upon the results of this sample data and are thereby subject to statistical, or inferential, error. This inferential error is divided into two types: noting a significant difference in the samples when there is none — Type I error, and the failure to note a significant difference when a significant difference does exist — Type II error. Attempts to limit the probability of Type I error (denoted by α) generally increase the likelihood of Type II error (denoted by β). The only way to simultaneously eliminate both types of error is to increase the sample size. The confidence intervals selected for the individual analyses attempt to balance the possibility of these two types of error. In those analyses where one type of error may have more serious consequences than the other, a confidence level is selected to limit the more severe of the two error types.

Analysis performed on the data to determine the frequency distribution of the findings and observations divides the data into several discrete categories, i.e., 17 subsystems. In addition, the sample sizes are relatively low; e.g., the sample size of domestic PC holders for FY 1998 is 44 facilities having a total of 121 findings and/or systemic observations among them. This already small sample size is further divided into the occurrences within 17 subsystems and 227 different criteria elements. A 95 percent confidence interval was used in order to highlight the differences among the various subsystems while maintaining a reasonable limit of Type II errors.

Some of the analyses in this report test for significant differences among a few (typically four or less) proportions in an attempt to highlight potential variations in the samples. Because of the consequences associated with Type II errors in analyses of this type, i.e., not noting a trend and consequently not acting on that trend, an emphasis is placed on limiting Type II errors and less emphasis is placed on Type I errors. Decreasing β , however, correspondingly increases α — the probability of Type I errors. The level of significance is therefore increased to $\alpha = 0.10$ rather than using $\alpha = 0.05$ used for the analyses mentioned earlier. The confidence level is accordingly set at 90 percent — $100*(1-\alpha)$.

Increasing α simultaneously reduces β — the probability that a difference in the distributions or a trend will be erroneously missed. The probability of Type I and Type II errors (α and β) is simultaneously reduced through the pooling of two consecutive fiscal years of data and by eliminating known outside variants, e.g., facility complexity. Therefore, by applying a 90 percent confidence level on carefully selected and pooled data, trends can be spotted and acted upon as soon as possible while maintaining a reasonable limit on Type I errors.

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